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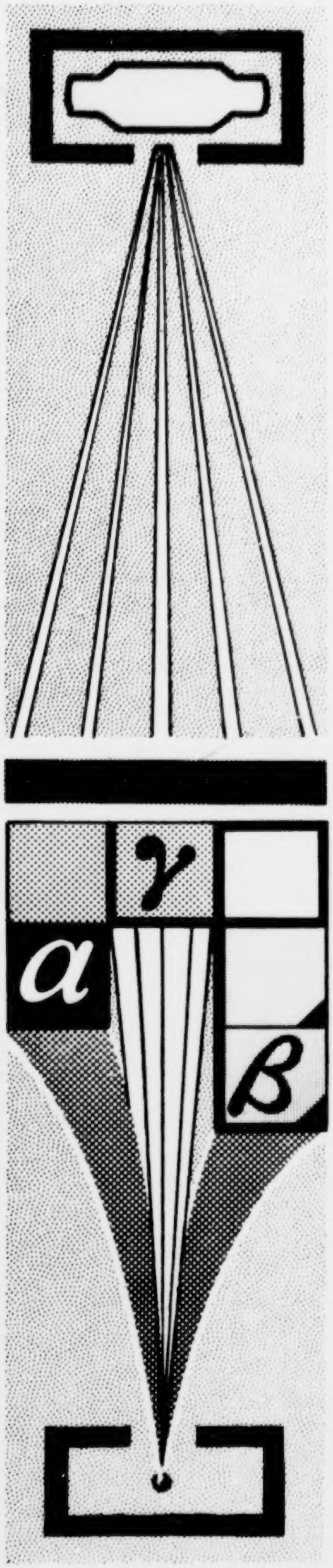

MEDICAL RADIATION INFORMATION for LITIGATION

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Public Health Service
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Environmental Control Administration

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MEDICAL RADIATION INFORMATION for LITIGATION

Proceedings of a Conference held on
November 21-22, 1968
at Baylor University College of Medicine,
Houston, Texas.

Edited by:

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Sponsored by
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and
University of Houston Bates College of Law

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U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Consumer Protection and Environmental Health Service
Environmental Control Administration
Bureau of Radiological Health
Rockville, Maryland 20852

FOREWORD

The Bureau of Radiological Health, formerly the National Center for Radiological Health, continues to carry out a national program designed to reduce the exposure of man to hazardous ionizing and non-ionizing radiation.

Within the Bureau, the Division of Medical Radiation Exposure deals with 1) the reduction of unproductive ionizing radiation exposure of patients, workers, and others exposed by the use of X-rays and other machine produced ionizing radiation, radioactive materials and radiopharmaceuticals, and 2) the improvement of radiological "systems" and methodology in the healing arts.

The Bureau publishes its findings in Radiological Health Data and Reports (a monthly publication), the Environmental Health Series, Public Health Service numbered reports, appropriate scientific journals, and Division technical reports.

The technical reports of the Division of Medical Radiation Exposure (DMRE), formerly the Medical and Occupational Radiation Program (MORP), allow comprehensive and rapid publishing of the results of intramural and contractor projects. The reports are distributed to State and local radiological health program personnel, Bureau technical staff, Bureau advisory committee members, university radiation safety officers, libraries and information services, industry, hospitals, laboratories, schools, the press, and other interested individuals. These reports are also included in the collections of the Library of Congress and the Clearinghouse for Federal Scientific and Technical Information.

I encourage the readers of these reports to inform the Bureau of any omissions or errors. Your additional comments or requests for further information are also solicited.

John C Villforth

John C. Villforth
Bureau Director

PREFACE

The Conference on Medical Radiation Information for Litigation was held to promote an exchange of opinion between experts in the medical-scientific and legal fields. The basic topic was the present content, accessibility, and usefulness of individual medical radiation exposure records. In addition, considerations of radiation monitoring and validity of radiation measurements were superimposed over requirements of legal proof, in order to examine the interrelationships. Papers presented on the first day were devoted to pertinent medical and scientific problems, while questions of law were considered during the second day.

These proceedings include the formal presentations, edited transcripts of the discussions, letters submitted after the Conference to clarify certain points raised, and a list of Conference participants.

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ABSTRACT

A two day conference, November 21-22, 1968, sponsored jointly by the Baylor University College of Medicine and the University of Houston Bates College of Law, explored the feasibility of collecting and maintaining records of medical radiation exposure for purposes of potential litigation. This conference was convened at the Baylor University College of Medicine in Houston, Texas. Invited attendees included representatives from medical, scientific, governmental and legal communities.

The first day of this conference related to medical and scientific factors involved in radiation dosages, disease responses, monitoring instrumentation and records keeping. The second day of the conference related to litigation aspects of tort and workmen's compensation liability, causal and proof problems, factors pertinent to litigants and the application of current legal doctrines to the problem.

The papers and the discussions revealed both areas of accord and of contention. Particularly highlighted were the intrinsically different objectives sought in connection with radiation records keeping by the medical-scientific and legal professions. Of primary importance was the lack of agreement among the medical-scientific community as to the magnitude of the hazard arising from radiation exposure, especially in terms of latent effects. The lawyers felt that the causal relationship between radiation and disease had not been sufficiently documented to constitute legal proof, as presently defined. Answers to this problem were suggested in alternative proposals for reform such as reduced requirements necessary to satisfy legal proof, more comprehensive insurance programs or substantial revisions of the law relating to liability.

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FIRST SESSION - MEDICAL AND SCIENTIFIC ASPECTS

OPENING REMARKS

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The title of this conference indicates a medical area that presents some distinctive legal problems. The subject is radiation and the problem is radiation injury. The public's concept of ionizing radiation surrounds it with an aura of mystery that invites a measure of exploitation for attention by lay and scientific press alike and this despite continuing investigation that is as intensive and thorough as any area in all of medicine. The law is concerned with radiation as a dangerous agent and would deal with it as any other, if only medicine would provide some simple answers to simple questions. Does the plaintiff, client, patient, workman, or passer-by, have an injury? Was he exposed to radiation? Did radiation cause the injury? Which radiation, or whose radiation, caused the injury? When did the injury occur or when will it, or could it, occur?

No particular problem exists where the circumstances and time relationship of an acute radiation effect are credible as to causation and acceptable under statutes of limitations for other injuries. But for exposures that produce no immediate or observable effect, radiation has been blamed for many ensuing ills that also occur spontaneously or due to other agents in the common environment. Freedom from any detectable sign of injury may not allay apprehension for a much delayed effect of radiation. There is apt to be exaggerated concern in this regard, although the population calmly co-exists with the late effects of drugs, alcohol, tobacco and environmental pollution.

It must be recognized that whatever information is available, two answers are sought under our adversary system of litigation, and differences in opinion and interpretation that peacefully co-exist in shades of grey will be exploited to the black and white of "Yes it is", and "No it isn"t".

The answer given may come to rest in any of several states

- It may be correct and believed by the court
- It may be correct but not believed

- It may be correct and misrepresented or misinterpreted
- It may be correct but irrelevant and not significant
- It may be in error and rejected
- It may be in error but accepted.

The role of the expert witness for medicine or science is to prepare and present the information that the court and parties require. It is also his opportunity and obligation to impart the understanding that will allow the court to use properly the information presented.

Injury and proof may be sought and found in medicine or law but injury in law is inclusive of injury in medicine and more.

Injury: Any wrong or damage done to another, either in his person, rights, reputation or property.*

Law can find proof where medicine and science cannot, because medicine can wait, and must, for the slow unfolding of progress in research whereas law must answer today's dispute with today's opinion of today's evidence.

Proof: The conviction or persuasion of the mind of a judge or jury, by the exhibition of evidence, of the reality of a fact alleged. **

The machinery of law requires what information medicine has and our conference is to present what information medicine has on the subject of radiation that is useful for the purposes of litigation. But if medical information on radiation must be submitted to find legal injury and legal proof, then legal usage of this information should not distort the medical intent or exploit the developing fund of scientific knowledge.

A crucial feature of our discussion is the matter of dose. Dosage is as old as the practice of medicine and it is based on experience, empiric or most carefully tested, that for a carefully prescribed amount of a given agent, a predictable biologic effect will occur. Successful medical treatment hinges on the correctness of this prediction.

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* Hitch v. Edgecombe County 132 N.C. 573, 44 S.E. 30

** Ellis v. Wolfe-Shoemaker Motor Co., App. 508, 55 S.W. 2d 309

Dose involves measuring the therapeutic agent. There are in fact no units of dose as such, but only units of measurement appropriate to the agent, units of weight, units of volume, units of energy. In our case the unit appropriate to the interaction of ionizing radiation and matter, is the roentgen, the rad or the rem.

It is essential that the time element be included in the prescription (A prescription of 150 grains of aspirin for a cold could be dangerously misinterpreted but 10 grains t.i.d. for five days might be reasonable and effective).

It is inherent in the concept of dose that it be given to a living biologic system (A dose of nitroglycerin is prescribed for angina pectoris but not to blow a bridge. In a radiograph of the chest, the exposure to the patient is expressed as a dose of radiation but the film exposure is not referred to as a dose).

Prescription of dose envisages a particular biologic effect. The dose of a given agent varies with nature of the disease to be treated (Aspirin for headache or aspirin for rheumatoid arthritis).

Dose is the amount of an agent, given in a specified time, to a living system or organism, to produce a predicted effect.

Dose is a concept that one may equate a physical agent and a biologic effect; that if one duplicates or manipulates all the factors of measurement of the agent and if one is cognizant of all the biologic variables in response then a predictable relationship exists. To the degree that the quantitation of administered agent is uncertain, and biologic system is in flux, the prediction diminishes from certainty to statistical probability to a mere possibility.

The lawyer knows the ancient law school story of the examination where questions are always the same but the answers change.

He should have no problem grasping the nature of the dose. It cannot be described in a single numerical value. The dose may vary while the number remains the same, and the dose may be the same even if the number changes.

In seeking causation between radiation and injury the patient's history is closely searched for any record of his exposure and when dose is abbreviated to a single numerical value the temptation to add may lead to a head-on collision of reason and arithmetic.

We have said that the certainty of the predictable relation lies in the totality of the description of the physical agent and the biologic effect.

If the information in the medical record does not reach to a total description, still we can improve the content of the medical record to the limit of our ability and we can use all of the available information to best effect for the particular question being litigated.

CHARACTERISTICS OF RADIATION MONITORING INSTRUMENTATION AND METHODS

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I. INTRODUCTION

In order for radiation dose measurements to be meaningful, they must of course be related to some biological effect of interest. In the early days of this century, soon after the discovery of x-rays and radium, it was recognized that the absorption of x-rays produced free electrical charges in air by ionizing air molecules. Such ionization of course required the absorption of energy from the radiation, and we now know that many biological effects can be related to absorbed energy in tissue, which turns out to be proportional to absorbed energy in air for a given type of radiation and geometry. These phenomena led to the development of physical instruments for measuring ionization in air, which would then be used by biologists to define their radiation exposures quantitatively.

When, in turn, the biologists reported the particular biological effect observed, they could then express their results quantitatively in relation to the amount of "dose" delivered to the animal or system. Repeated experiments show that many biological effects could be thus related to a physical ionization measurement in a repeatable way (within certain limits of biological variation and/or experimental accuracy). Also, a biological effect was usually observed to increase in a one-to-one manner when the dose increased.

However, the shape of the "dose-response" curve obtained when plotting some measured response as a function of dose could differ depending on the experimental factors involved, such as: the rate of delivery of dose, the type of radiation, the quantum energy of the radiation, the strain of animal or type of tissue and many other factors.

The nature of some of the more important dose-response relationships for humans will be reviewed by Dr. Stewart Bushong in more detail in the following paper. At this point, we need to understand only that our radiation monitoring instruments must essentially be designed to make specific dose measurements for types of radiation of interest. They must be designed to have a physical response proportional to the expected biological response, or the probability of a biological response.

Thus, the science or technology of radiation monitoring is inextricably bound up with the science of radiobiology and radiation physics. Many types of radiation monitoring instruments are required for special situations in order to approximately match some of the complexities of the dose-response relationships of interest.

Generally speaking, instruments for monitoring radiation exposures of employees in their occupational environments are allowed wider limits of error and are compensated by factors of safety, so that relatively fewer instrument designs can be utilized and portable equipment can be manufactured for radiation survey purposes. Certain radiation measuring devices have also been developed that may be worn by the individual employee in order to obtain a closer assessment of actual exposure; these are called "personnel monitoring devices".

In this paper, we shall discuss some of the basic principles of radiation measurement for purposes of protection. Then we will show examples of some of the radiation monitoring instruments used, and provide some comments on the relative precision with which radiation dose measurements may be made. Indeed, we must also consider the precision that may be warranted in consideration of the variability in biological response of even a single strain of organism exposed to a single type of radiation. More detailed discussions of radiation responses and units of dose measurement will be presented by Drs. Stewart Bushong and Donald Willhoit. Also, a more comprehensive summary and references for further study have been submitted for publication in the conference proceedings.

II. UNITS OF RADIATION MEASUREMENT

A number of acute and long-term effects on animal and human species have been related to the physical energy absorbed from various types of ionizing radiation. However, the relative effectiveness of each type of radiation per unit energy absorbed in biological tissue has been found to vary not only with the type of radiation and its quantum energy, but also with the rate at which the energy is delivered, the kind of tissue, the age and species of animal, the biological effect under consideration, and other experimental and epidemiologic variables. For mammals, beta-radiation and the recoil electrons ejected from atoms by x- or gamma radiation generally produce approximately the same order of magnitude of biological effects. On the other hand, heavier particles, such as the alpha particles emitted by certain radionuclides, lose their energy at higher rates of linear-energy-transfer (LET) along their paths, and seem to produce somewhat higher damage per unit energy absorbed. Of course, in the case of alpha-emitting radionuclides, since the characteristic alpha particles emitted do not have sufficient range to penetrate the dead layer of skin, alpha emitters produce biological damage only when the radioactive material itself is distributed within an organ by the inhalation or ingestion of the radioactive material.

Thus, for purposes of radiation hazard evaluation, several units of radiation exposure and dose must be introduced to account for the several methods of measuring and assessing the effects of different types of radiation. Since most radiations of a given type, as emitted by most radionuclides, have average LET's within a narrow range, and consequently seem to have relative biological effectivenesses (RBE's) within a narrow range, characteristic simplifications can be introduced to limit the number of new units and definitions required for most applications.

In this presentation, the following dose units will be utilized. These units will be explained by Dr. Willhoit:

Roentgen (or "R") - a unit for expressing exposure from x- or gamma radiation in terms of the ionization produced in air (1 e.s.u/cc), which can be measured by appropriate air ionization chambers and electrical instruments. It is defined as an exposure "such that the associated corpuscular emission per 0.001293 g of air produces, in air, ions carrying one electrostatic unit of quantity of electricity of either sign."(1) This simply means that an exposure (formerly called "exposure dose"(2)) of one roentgen (R) generates recoil electrons per 0.001293 g of dry air within a small volume surrounding the point of measurement such that these electrons produce in air 1 e.s.u. of positive charge and 1 e.s.u. of negative charge (as ion pairs). Since many electrons will leave the element of volume before losing all of their energy, in order to most accurately measure the roentgen, a "standard air chamber" is necessary (schematically illustrated in Figure 1). This chamber is specially designed to achieve an "electronic equilibrium" condition in which the ionization within a specific volume of air is collected, and the ionization lost by electrons leaving that volume is compensated for by an equilibrium number of electrons entering the volume from a preceding volume of air.(1) Thus, the roentgen is a unit that expresses a point quantity, essentially the ionization density produced near the point of measurement in air. When applied to human exposure in a large beam or field of radiation, either the field must be uniform or the exposure in R must be measured at each point in the field. In summary, the roentgen may be remembered for practical purposes as the x- or gamma exposure producing 1 e.s.u. (+ or -) per cc of air (at STP of 0°, 760 mm Hg).

rad - a unit of "absorbed dose" (D) in any medium for any kind of ionizing radiation.(1,2) It is simply defined as

1 rad = 100 ergs/gram

Integral absorbed dose - The integral $\int D\,dm$ over an organ, or the whole body, where D is the variable absorbed dose within mass element dm. It is useful in obtaining an idea of the total energy absorbed by a region of tissue, which is more closely related to certain macroscopic biological changes than the dose only near one point. Common units are gram-rad, and 1 gram-rad = 100 ergs. The integral absorbed dose may be divided by the total mass of tissue in the region of interest to obtain the average tissue dose $\bar{D}$ in rads.

rem - a unit of "RBE-Dose" or "Dose-Equivalent (DE)", used to express the estimated equivalent of any type of radiation that would produce the same biological endpoint as 1 rad delivered by x- or gamma radiation. Thus,

$$\text{DE(in rem)} = \text{Dose (in rad)} \times \text{QF} \times \text{DF},$$

where QF (formerly called RBE) accounts for the relative biological effectiveness of the radiation compared to x-radiation for radiation protection purposes; and the DF (formerly designated n) is the "relative damage factor,"(3) or "distribution factor"(1,2) used to account for differences in the distribution of the "rad" dose to the organ of concern as a result of uneven uptake of the radionuclide, etc., as opposed to the QF or RBE factors reserved for more intrinsic biological characteristics of the emitted radiations.

gram-rem - The units for integral absorbed dose when several types of radiation are involved and the equivalent doses of each are to be added after multiplication by appropriate relative biological effectiveness factors.

Curie (Ci) - The most common unit used to express the radioactivity (A) of a material; it is the amount of any radionuclide(or combination of radionuclides) in which there are 3.7×10^{10} nuclear transformations or disintegrations per second (also, 2.22×10^{12} disintegrations/minute or "dpm"). The following prefixes are commonly used as for other scientific units:

1 Megacurie (MCi) = 10^{6} Ci
1 Kilocurie (KCi) = 10^{3} Ci
1 millicurie (mCi) = 10^{-3} Ci
1 microcurie (μCi) = 10^{-6} Ci
1 nanocurie (nCi) = 10^{-9} Ci
1 picocurie (pCi) = 10^{-12} Ci

The above prefixes are widely used since we deal with a wide range of quantities of radioactivity in evaluating radiation exposure potentials.

A more detailed discussion of units and their significance will be covered by Dr. Donald Willhoit in a following paper. The above definitions will suffice for our general discussion of monitoring methods.

III. PHYSICAL MEASUREMENT OF DOSE

A. Basic Principles

The standard air chamber, described in Figure 1, is the standard instrument for measuring exposure in Roentgens. It is a relatively large, expensive, and sensitive instrument, and since measurements of the Roentgen apply directly only to x- or gamma rays, many other field and laboratory instruments have been devised for measuring the absorbed dose or dose-equivalent from various types of radiation, although in some cases less precisely. Instruments have also been designed to measure over wide ranges of intensity and energy. Some of the methodology

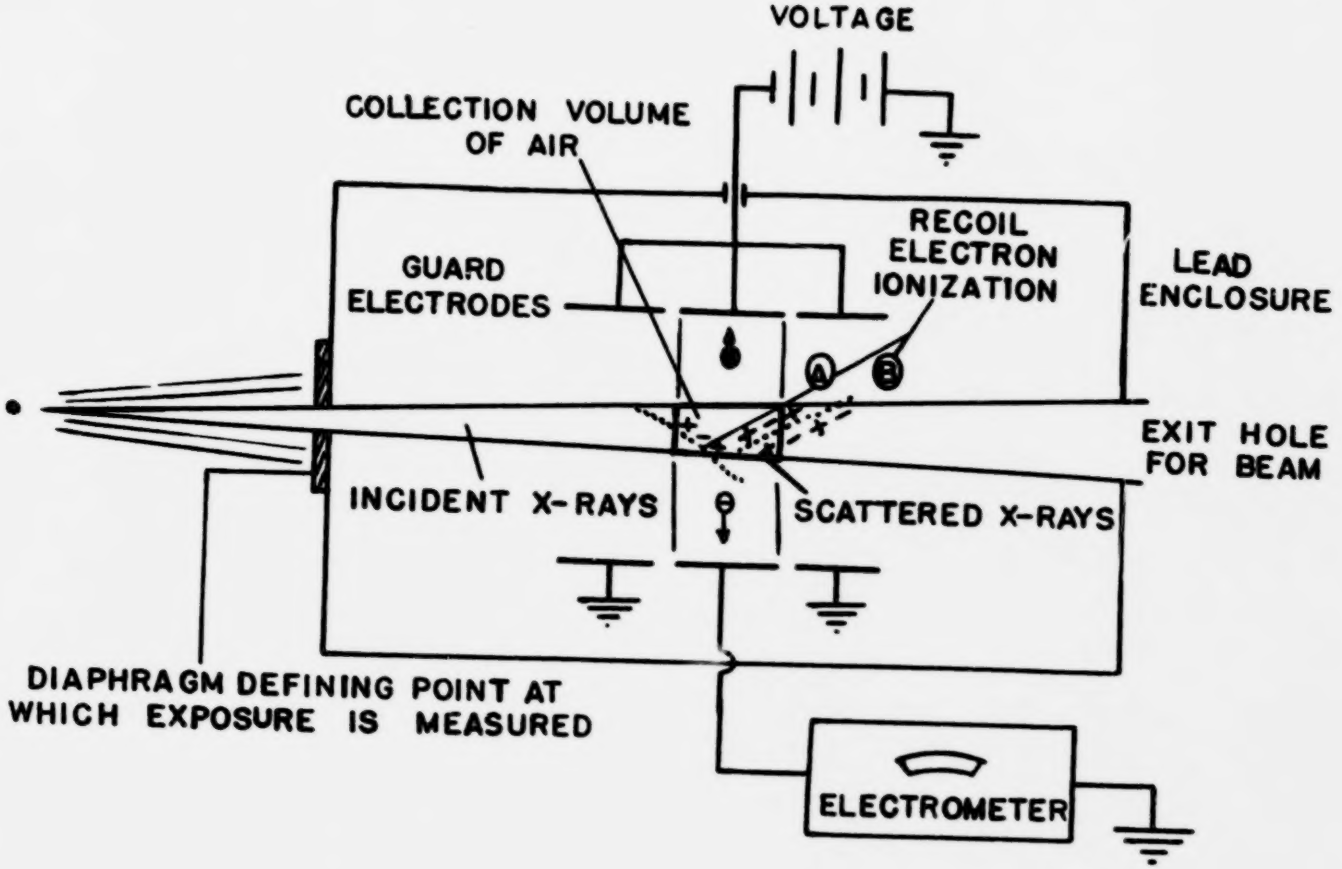
VOLTAGE
COLLECTION VOLUME OF AIR
RECOIL ELECTRON IONIZATION
GUARD ELECTRODES
LEAD ENCLOSURE
A
B
EXIT HOLE FOR BEAM
INCIDENT X-RAYS
SCATTERED X-RAYS
DIAPHRAGM DEFINING POINT AT WHICH EXPOSURE IS MEASURED
ELECTROMETER

Figure 1
Schematic Diagram of a Standard Air Chamber for Primary Measurements of X-Ray Field Exposure Rates in Terms of Roentgens/Hour. The diaphragm defines the point at which the R/hour intensity is to be determined; the guard electrodes ensure a uniformly parallel electric field for collecting ions produced and remaining in a defined collection volume of air.

has been reviewed in References 4-9.

Small cavity chambers with air-equivalent or tissue-equivalent walls have often been used as secondary-standard instruments for measuring radiation exposure or absorbed dose. The ionization collected by an electrode within a small cavity in a suitably-designed chamber can be related to the energy deposited per gram of wall material. Also, the relationship may hold constant for a wide range of energies as long as certain Bragg-Gray conditions(8) are fulfilled.

In its simplest form the Bragg-Gray principle states that the ratio of the energy absorbed per gram of a medium to the energy absorbed per gram of gas in a small cavity in the medium is constant (almost independent of the initial energy of the recoil electrons produced in the medium). Since the energy W_g to produce an ion pair in a gas is also apparently independent of energy, we have the Bragg-Gray Principle(10)

$$E_m = S_g{}^m \cdot W_g \cdot J_g,$$

where E_m = the energy absorbed per gram of wall material; $S_g{}^m$ = the relative mass stopping power ratio $(dE/\rho\, d\ell)_m/(dE/\rho\, d\ell)_a$ for electrons in the material and in air (i.e., the ratio of the rates of energy loss per unit path measured in grams/cm^2); W_g = the average energy required to produce an ion pair in the gas, now usually taken as 34 e.v./ion pair,(8) and J_g is the number of ion pairs produced per gram of gas in the cavity. Average mass stopping power ratios are given in References 10 and 11, for electrons of various initial kinetic energies.

The conditions(10) to be met for the Bragg-Gray relation to hold are briefly:

(a) Cavity dimensions must be small compared to the ranges of most secondary ionizing particles;
(b) Most ionizing particles should originate in the chamber walls, and very few primary interactions should occur in the gas;
(c) The fluence of primary and secondary particles should be nearly uniform across the cavity; and,
(d) The wall of the cavity should be thick enough so that all recoil charged particles traversing the cavity originate within the wall material, but the wall must not be so thick that it attenuates the primary non-ionizing radiation appreciably.

Cavity-chambers may be made with walls having an average atomic number Z simulating that of soft tissue so that they can measure the "rad" dose more directly. More often, however, "R" chambers having air equivalent walls are used, with appropriate wall thicknesses for the x- or gamma-ray energies to be measured. Then the exposure or "air-dose" measured in roentgens (R) can be converted to the appropriate absorbed dose in tissue in rads by the equation(10)

$$D_{tissue}\ (\text{rads}) = 0.877 \times \frac{(\mu_{en}/\rho)_{tissue}}{(\mu_{en}/\rho)_{air}} \times R$$

$$= f \cdot R,$$

where (μ_{en}/ρ) is the mass energy absorption coefficient for the particular gamma-ray photon energy for tissue and air, respectively. Some f factors and values of m $\mu_{en} = \mu_{en}/\rho$ for various materials and gamma-ray energies are given in References 10 and 11.

When exposure to x- or gamma radiation is measured at or near the surface of the body with an air wall chamber of "equilibrium" thickness, the dose in rads at various depths in tissue must be corrected for attenuation by the use of depth-dose curves or tables. However, the fractional dose at each depth depends not only on the quantum energy of the radiation, but on the area of the beam at the body surface, the source to skin distance, and other factors.(2,10) Depth-dose tables are given in Johns.(10) The equivalent kilovoltage (effective Kev) corresponding to the half-value-layer (HVL) of aluminum, copper, or lead required to absorb half the radiation intensity is illustrated in Figure 2. Table 1 illustrates the relationship between photon fluences and exposures in Roentgen units. Depth-dose data and conversion factors for many other conditions may be found in the references cited.

The fundamental theory of radiation dosimetry is described in much further detail in References 1-13.

B. Personnel Dosimetry

The general principles of radiation detection and dosimetry have now been described. In the field of radiation protection, various devices have been developed to be worn by personnel in order to obtain a more direct estimate of their radiation exposures, in order to: limit their cumulative lifetime exposures from routine operations to within the average of 5 Rem/year (5(N-18) cumulative after age 18) recommended by the NCRP; detect increasingly hazardous situations or unexpected incidents; and provide a record of the degree of protection afforded by the employer's facility. These personnel monitoring devices are designed to be small and wearable, and to measure over the widest range of types and amounts of radiation exposure to which the employee may be exposed. Thus, for control purposes, a wider degree of error in assessing the actual dose-equivalent in Rem must be accepted. This is a result of the limited number of devices or filters that can be incorporated in a personnel dosimeter, which may be required to detect multiple types of interactions from various types or energies of ionizing radiation. Usually, when accuracy must be compromised for certain types or quantum energies of radiation, the personnel dosimeter is designed with sufficient safety factors in its method of readout or interpretation, so that radiation exposures at the position where the badge is worn on the body are more likely to be conservatively overestimated when in error at all.

From the technical complexities indicated by the above considerations, as well as the principles of dose assessment discussed before, one can understand why the subject of personnel dosimetry is itself a field of specialization within the health physics (radiation protection)

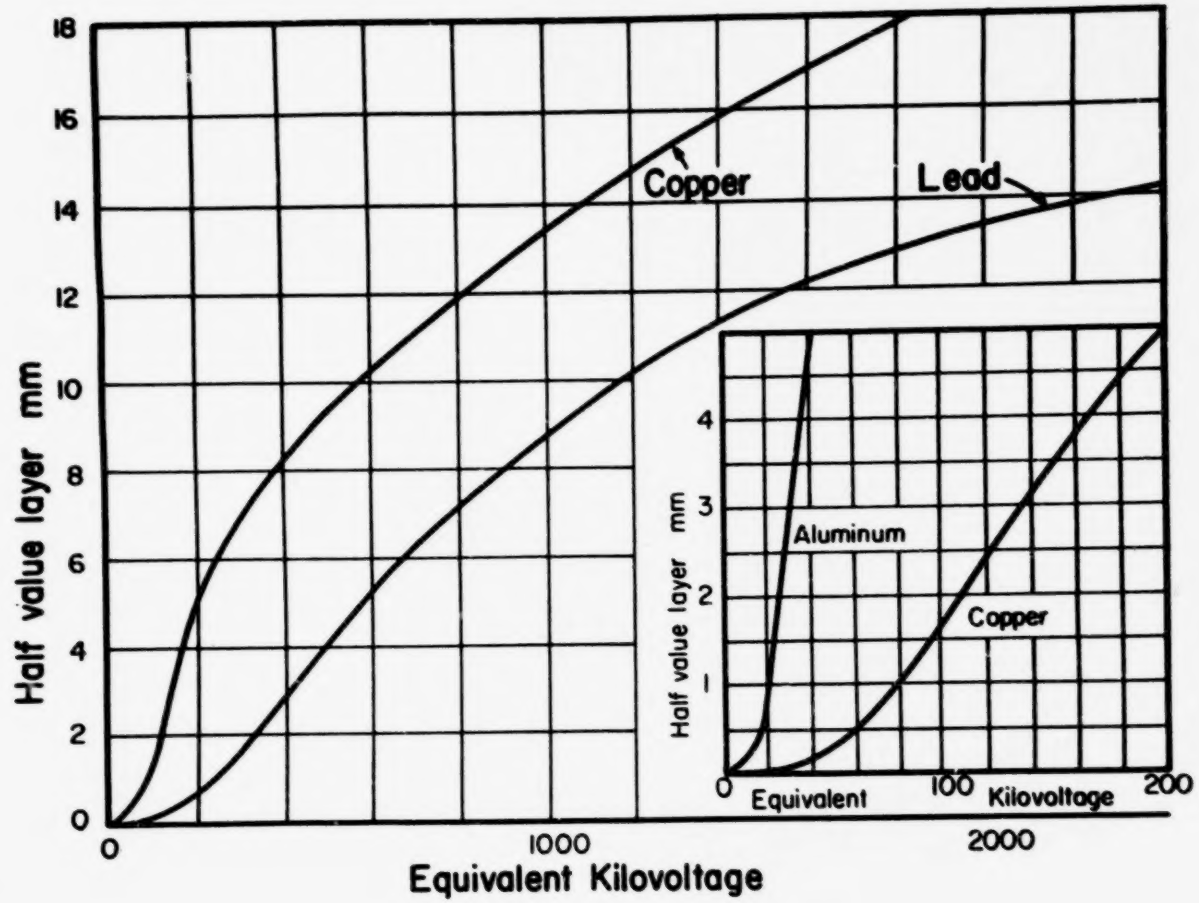

Figure 2
Relationship Between Equivalent Kilovoltage, Represented by the Average Absorption Coefficient for a Spectrum of X-Rays, and Half-Value Layer (From Johns, H. E., THE PHYSICS OF RADIOLOGY, 2nd. Ed., 1964. Courtesy of Charles C. Thomas, Publisher, Springfield, Ill.)

Table 1

Energy Mev	Energy Absorption Coefficient $(\mu_{en})_{air}$	Photon Flux per Roentgen (No./cm^2 per R)	Roentgens per hour per millicurie at 1 cm
0.01	4.66	11.7×10^8	9.02
0.02	0.516	53.1×10^8	2.00
0.04	0.064	214×10^8	0.495
0.06	0.0292	313×10^8	0.339
0.08	0.0236	290×10^8	0.365
0.10	0.0231	237×10^8	0.447
0.20	0.0268	102×10^8	1.09
0.40	0.0296	46.3×10^8	2.29
0.60	0.0296	30.9×10^8	3.44
0.80	0.0289	23.7×10^8	4.47
1.0	0.0280	19.6×10^8	5.42
2.0	0.0234	11.7×10^8	9.05
4.0	0.0186	7.36×10^8	14.4
6.0	0.0163	5.60×10^8	18.9
8.0	0.0150	4.57×10^8	23.2
10	0.0144	3.80×10^8	27.9
20	0.013	5.3×10^8	
40	0.013	11×10^8	
60	0.014	17×10^8	
100	0.015	30×10^8	

Table 1

Theoretical Values of the Energy Absorption Coefficient for X and Gamma Rays in air, the photon flux per roentgen, and the roentgens per hour per millicurie at 1 cm from a point source (From H. E. Johns, The Physics of Radiology, 2nd Ed., C. C. Thomas, Springfield Ill., 1964, p. 694, and American Institute of Physics Handbook, Dwight E. Gray, Ed., McGraw-Hill Book Company, N. Y., 1957).

profession. A number of texts are already available to introduce the scientific and technical considerations of personnel dosimetry. (4,5,6, 7,8,10,12,13,14,15,16,17,18). In this section, we shall briefly describe only the more frequently utilized devices. There are more than a dozen firms offering film badge, thermoluminescent dosimeter, or other personnel monitoring and record-keeping services on a commercial basis throughout the world. These firms may be contacted through journal advertisements or through the Film Dosimetry Testing Services, National Sanitation Foundation, University of Michigan, Ann Arbor, Michigan.

The first type of personnel monitoring device routinely utilized in the atomic energy laboratories after the discovery of nuclear fission was the pocket-type or "pencil" ionization chamber. These pocket chambers consist of a center electrode charged to perhaps 150 volts, positive with respect to the outer cylindrical wall. The center electrode has a miniature quartz-fiber electroscope attached to it, so that the deflection of the quartz fiber decreases with increasing radiation exposure. The degree of loss of charge may be read out by connecting the chamber to a separate charger-reader, or electrometer. Some "self-reading" chambers, or "pocket-dosimeters" contain a built-in microscope and scale by which the position of the quartz fibers may be read by the wearer at any time, simply by looking through the chamber toward a light source.

Chambers are made with various types and thicknesses of wall material, depending on the type of radiation to be measured. Special chambers coated inside with Boron-10, which absorbs slow neutrons and emits heavily ionizing alpha particles, may be used in the presence of some gamma radiation to detect neutron exposures. Pocket chambers of various types and ranges are available commercially. They are valuable for obtaining an immediate or daily assessment of individual exposures, as well as for area monitoring. When high accident-exposure potentials are present, or where independent assessment and recording of longer-term cumulative exposures are desired, pocket chambers are supplemented or replaced, as appropriate, by badges containing film, devices that can integrate exposures over a wide dynamic range. An illustration of a typical pocket dosimeter for measuring occupational exposures to gamma radiation is presented in Figure 3.

Probably the most widely used personnel dosimeter at present is the film badge, a badge containing selected films in a packet similar to those used for taking dental x-rays. Usually the badge contains several filters for use in determining the relative penetration of the type of radiation being measured or for discriminating between types of radiation in such a way that corrections can be made in estimating the dose at the skin surface, and at various depths beneath the skin. A summary of the techniques of film badge dosimetry is

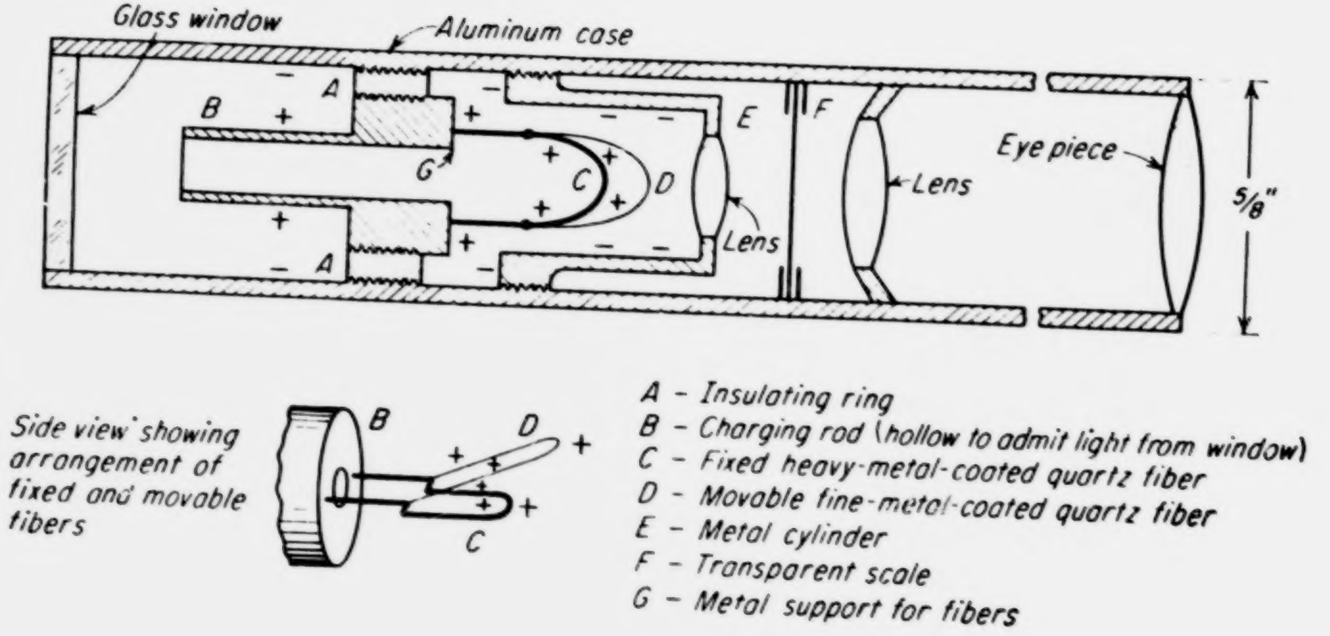
Glass window
Aluminum case
A
B
G
C
D
E
F
Lens
Lens
Eye piece
5/8"
Side view showing arrangement of fixed and movable fibers
B
D
C
A - Insulating ring
B - Charging rod (hollow to admit light from window)
C - Fixed heavy-metal-coated quartz fiber
D - Movable fine-metal-coated quartz fiber
E - Metal cylinder
F - Transparent scale
G - Metal support for fibers

Figure 3
Cross-Section of a Self-Reading Pocket Chamber. (From Price, W. J., NUCLEAR RADIATION DETECTION, 2nd Ed., 1966. Courtesy of McGraw-Hill, New York)

presented in Reference 18, and a more detailed and up-dated literature survey is presented in Reference 16. Figure 4 shows a series of photographs of a film badge and films exposed to different types of radiation. The following description of these photographs is taken from Reference 19:

> "The way films are used to monitor different kinds of radiation is really quite a simple process to illustrate. This fact helps make film easily accepted evidence in court.
>
> "Notice in Photograph 1 that the badge holder is composed of plastic front and back sections which tightly sandwich filters of copper and cadmiun on both surfaces of the film. The front filters are circular while the rear filters are rectangular.
>
> "Darkening of the entire film indicates gamma radiation (Photograph 2). If the cadmium filter is clear while the rest of the film is darkened, it is a sign of x-ray radiation (Photograph 3). If the area under both the cadmium and copper filters remains clear while the rest of the film is darkened, beta radiation is indicated (Photograph 4).
>
> "The subscriber is protected from erroneous results caused by light leaks, since this kind of exposure is easily identified. The exposure of a film packet resulting from a torn package wrapping is shown in Photograph 5.
>
> "Because of the use of differently shaped filters, exposure patterns can also indicate if the wearer was exposed to radiation from the back rather than the front of the body. Back exposure generally indicates that radiation penetrated the entire body before reaching the film and may have been strongly absorbed (Photograph 6).
>
> "Neutron monitoring is accomplished with special film which must be analyzed by direct observation. The neutron film is interpreted by an experienced technician who examines the special film with a microscope. The result of neutron bombardment shown in Photograph 7 has been enlarged 800 times."(19)

Although the development of improved or supplementary types of dosimeters should be continued, the photographic emulsion has many advantages in personnel dosimetry: relatively high sensitivity; wide range of exposure measurements; dose-rate independence up to 1000 R/sec or greater; possibilities for multiple-filter interpretations of energy and type of radiation; possibilities for a recheck of density readings or a professional re-examination of the nature of the photographic image as much as 25 years later;(75,85) low cost and ready availability; adaptability for automatic processing and reading in large quantities; and relative insensitivity to ordinary mechanical shock and vibration.(20) However, films are subject to certain fading and fogging characteristics at high temperatures or humidities unless they are protected by suitable wrappers.(21) Also for proper processing, a developing time of approximately 30 minutes is required, which may, in emergency situations or with a limited number of measurements to be made, be a (usually limited) disadvantage.

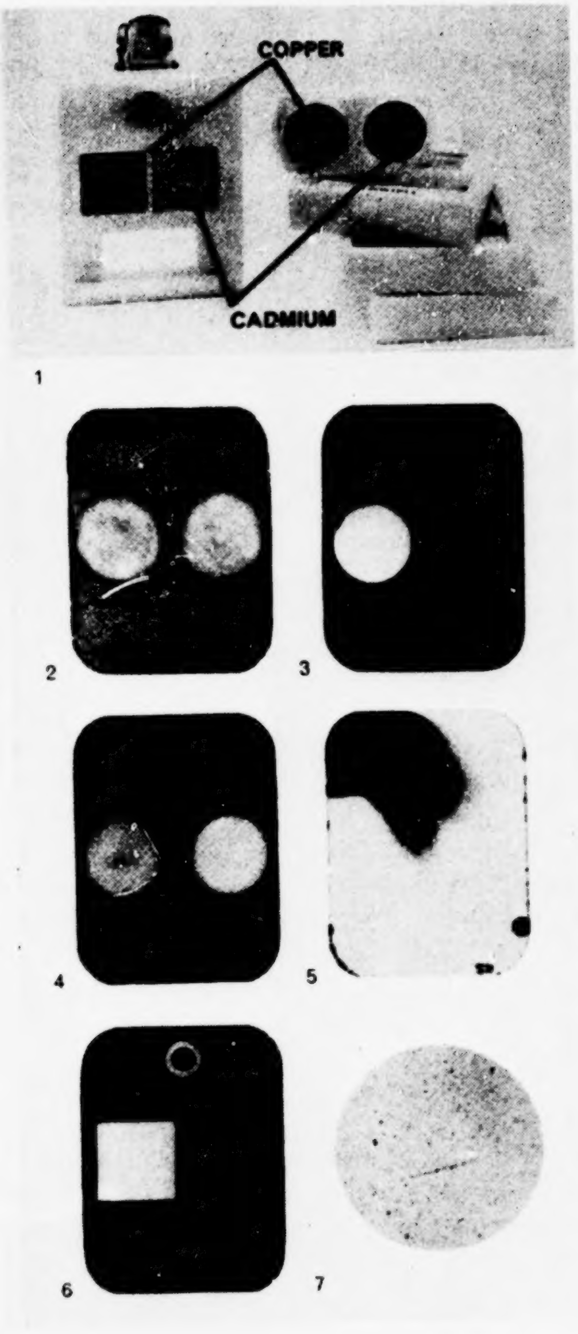

Figure 4
A Typical Commercial Film Badge and Developed Films Exposed to Different Types of Radiations and Situations (see text for discussion). Other types of badges may use different filter systems. (From Answers to Your Questions. Courtesy of Film Badge Division, Nuclear-Chicago Corporation, Des Plaines, Ill.)

Figure 5 shows the degrees of precision obtainable for duPont Type 555 personnel monitoring film when measuring weekly gamma ray doses over 12 week and 52 week periods, assuming that density readings are recorded to within about the nearest 0.001 density units. Often this degree of precision in density is not practicable under routine conditions, so somewhat less precision would be obtainable according to the instruments and procedures utilized. Figure 6 presents the precision obtainable for the more sensitive Kodak Type 3 film, for both a single film, a 12-week total and a 52-week total.(20) The confidence bands shown on Figure 7 are indicative of precisions obtainable with ordinary commercial equipment or procedures. The confidence bands on the log-log plot could also be superimposed on the x-ray curve at corresponding densities. The Kodak Type 3 packet also contains a more insensitive film for evaluating emergency exposures up to several hundred roentgens, but these calibration curves are not shown here. Figures 8 and 9 show additional response curves for other types of film used in personnel monitoring. In addition to the problems of protecting films from environmental temperature and humidity variations,(21) care must be taken to insure against the phenomenon of image reversal,(22) in which extremely high doses may bleach out latent images formed at lower exposures.

Within recent years, thermoluminescent materials have been developed that will measure gamma radiation exposure in the range of 10 mr to hundreds of roentgens or more with a fairly linear response. These dosimeters involve the use of a material that emits light when heated after irradiation, and the amount of light emitted is proportional to the amount of radiation exposure when heating conditions are kept constant. Figure 10 shows a schematic diagram of a thermoluminescent dosimetry (TLD) system, using a thermoluminescent powder which is deposited in pan A after it has been exposed to radiation.(23) Figure 11 shows some typical thermoluminescent glow curves, indicating the relative intensity of the emitted light as a function of temperature for various rates of heating. A number of different types of thermoluminescent dosimeters and their readers are now commercially available. The reader and dosimeters may be purchased, or a service may be subscribed to by facilities desiring an independent personnel monitoring service. Although the thermoluminescent dosimeter does not have the advantage of a photographic film in regard to the permanence and repeatability of the original density readings, the thermoluminescent powder or dosimeter may be annealed and reused after its glow curve has been read out. Thermoluminescent dosimeters are also useful for special studies where small dosimeters are implanted in or on phantoms for dose distribution measurements. A few dozen thermoluminescent dosimeters may be read out more quickly than the same amount of films since the read out time for each dosimeter is only about 30 seconds. However, when used in batches of several hundred or more, readout times are comparable for either thermoluminescent dosimeters or films, since films can be developed in batches of 1000 or more, and thus the time to obtain final results is limited mainly by the 20-30 sec/dosimeter to read each glow curve, or film

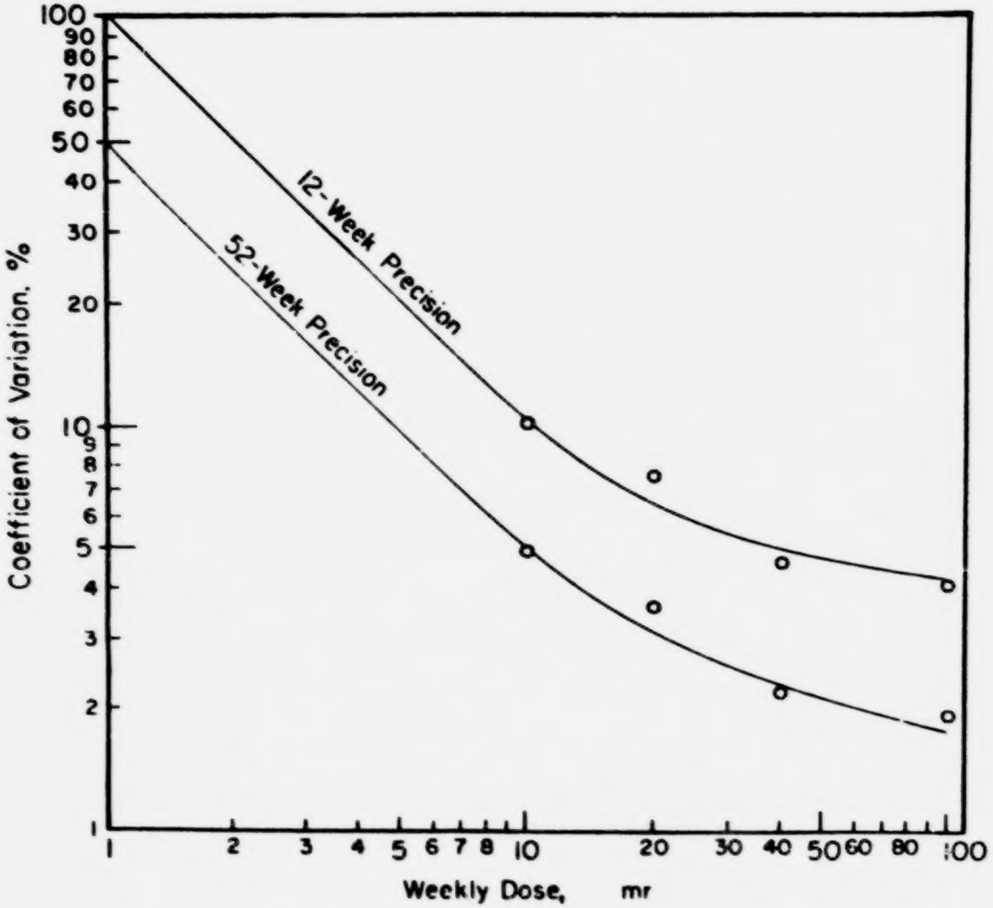

Figure 5
Precision of 12-week and 52-week Cumulative Dose Assignments from Weekly Films (From Brodsky, A., "Accuracy and Sensitivity of Film Measurements of Gamma Radiation--Part II, Limits of Sensitivity and Precision", Health Physics 9: 463-471, 1963. Courtesy of Pergamon Press, New York).

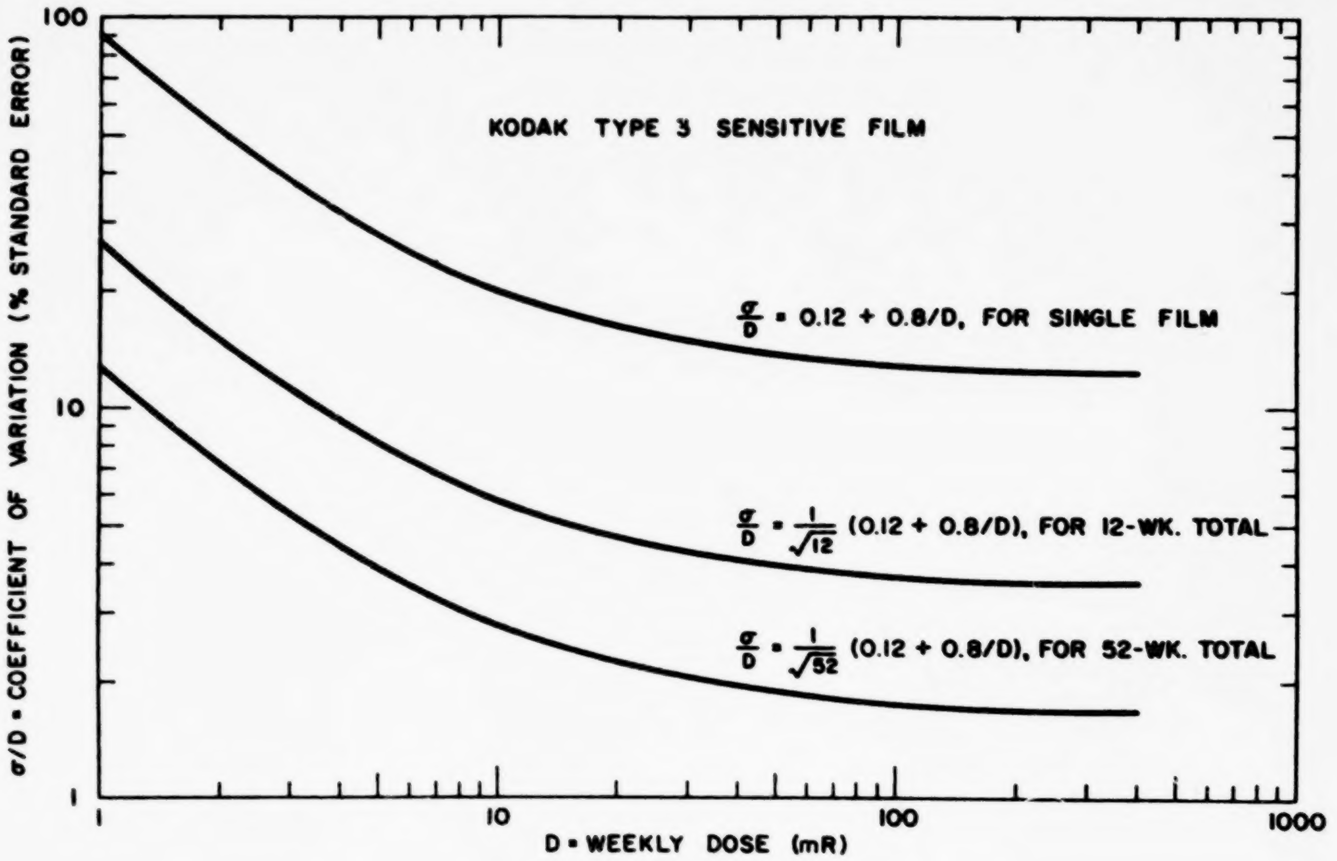

Figure 6
Minimum Percent Error vs. Weekly Dose to Films Evaluated on a Weekly Basis, for Total Wearing Periods of One Week, 12 Weeks, 52 Weeks. (From Brodsky, A., et. al., "Accuracy and Sensitivity of Film Measurements of Gamma Radiation--Part IV, Intrinsic and Extrinsic Errors", Health Physics 11: 1071-1082, 1965. Courtesy of Pergamon Press, New York)

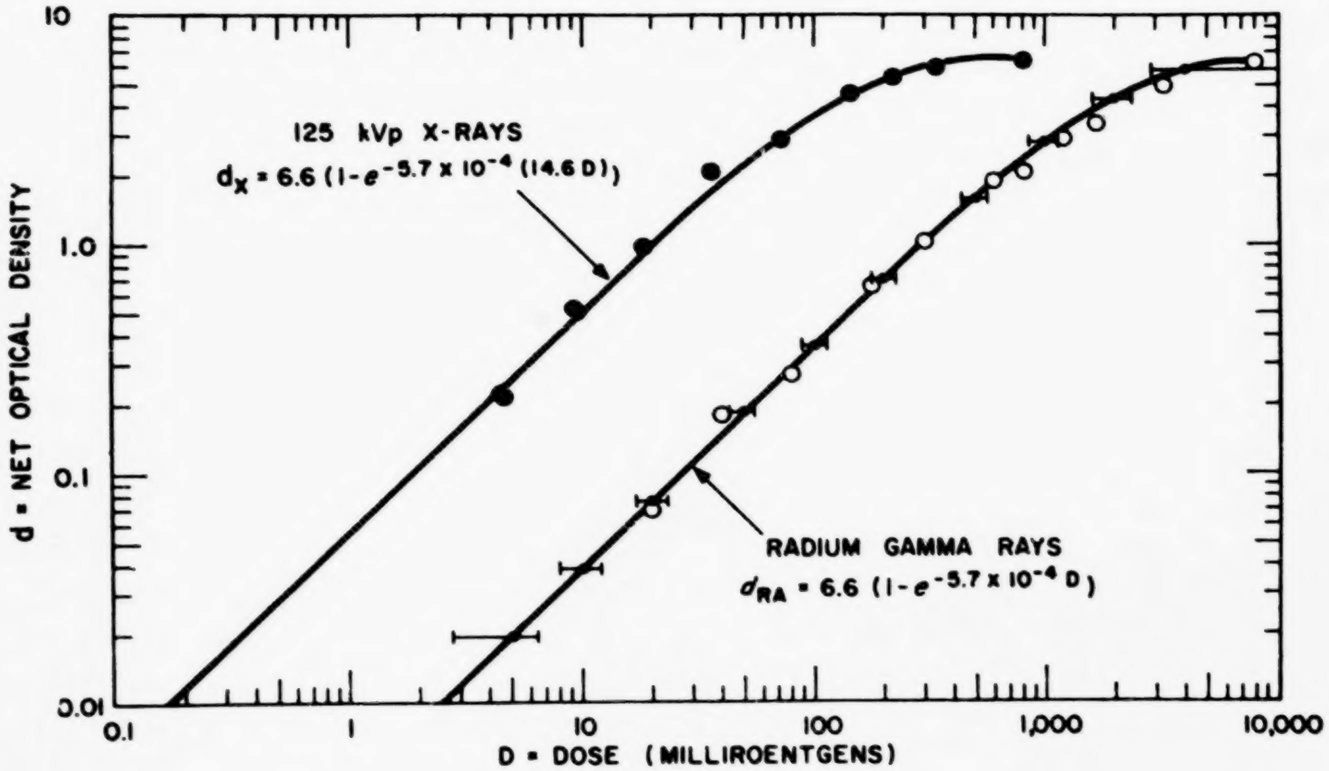

Figure 7
Net Density vs. Dose for Kodak Type 3 Sensitive Film, Developed at 68°F for 3 Minutes in duPont Liquid X-Ray Developer. (From Brodsky, A., et. al., "Accuracy and Sensitivity of Film Measurements of Gamma Radiation--Part IV, Intrinsic and Extrinsic Errors," Health Physics 11: 1071-1082, 1965. Courtesy of Pergamon Press, New York.) The confidence bands indicate the widths of the 68% confidence interval that may be placed about the average film interpretation at each density.

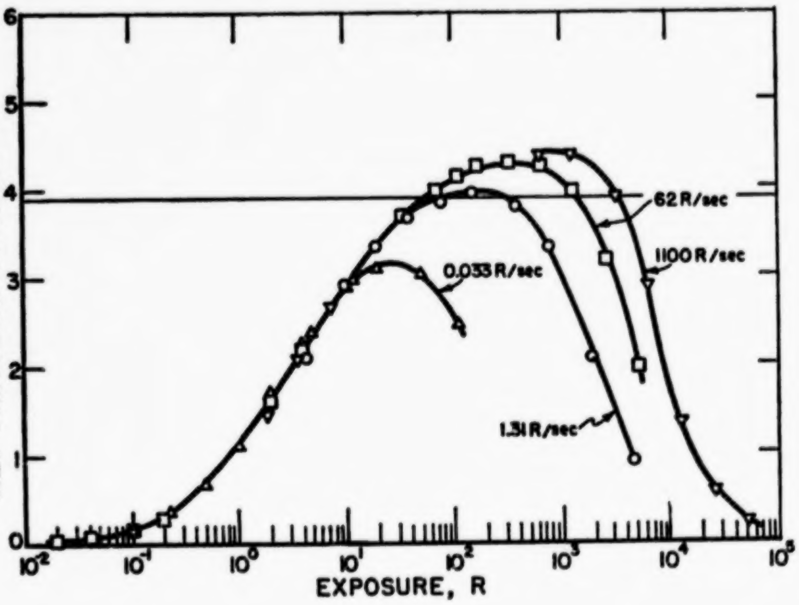

Figure 8

Net Density vs. exposure (roentgens) for duPont Type 502 film irradiated by 50-kV X-rays and developed in special surface-acting developer. Density is dependent on rate of exposure at high exposures (Ehrlich, 1963) (From Attix, F. H., Roesch, W. C., RADIATION DOSIMETRY, Vol. II, 2nd Ed., 1966. Courtesy of Academic Press, New York).

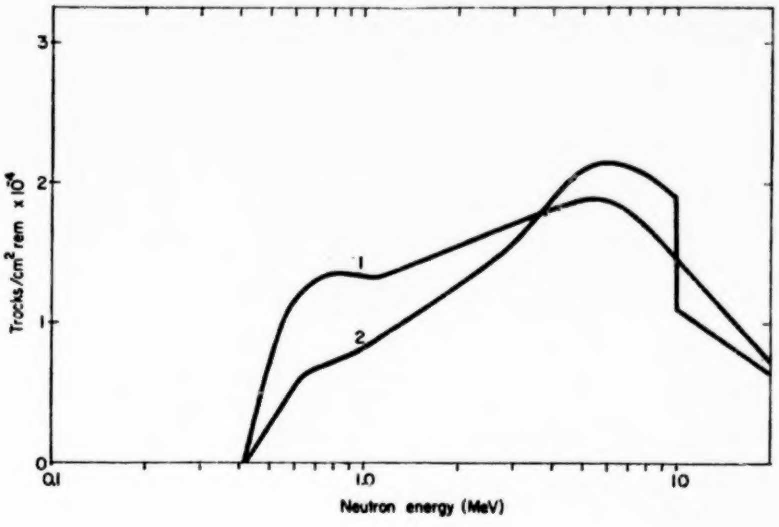

Figure 9

Tracks/cm^2-rem in Kodak Personal Neutron Monitoring Film, Type A, as a function of energy of perpendicularly incident neutrons. (Only tracks corresponding to >0.42 MeV protons were considered). Curve 1 is based on rem as calculated from kerma, assuming charged-particle equilibrium and a quality factor of 10. Curve 2 is based on rem at the surface of a phantom 30 cm thick--that is, on permissible fluence values in human exposure (Piesch, 1963). (From Attix, F.H., Roesch, W.C., RADIATION DOSIMETRY, Vol. II, 2nd Ed., 1966. Courtesy of Academic Press, New York).

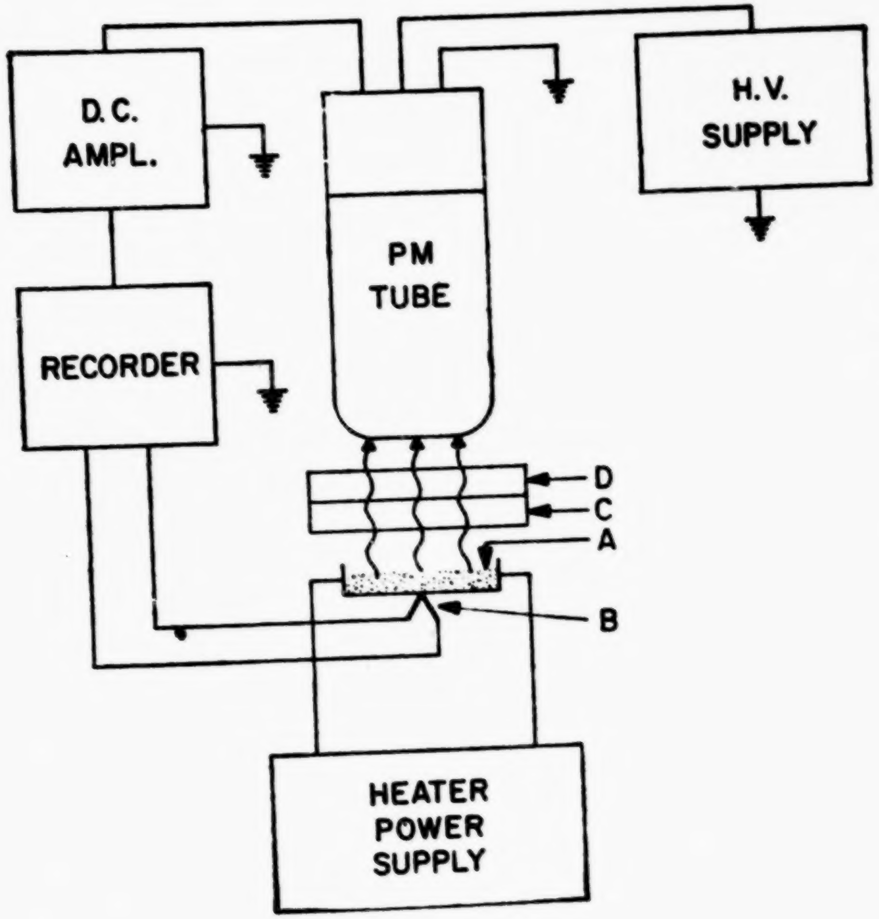
D.C. AMPL.
RECORDER
PM TUBE
H.V. SUPPLY
D
C
A
B
HEATER POWER SUPPLY

Figure 10
Typical Readout System for a Thermoluminescent Dosimeter. (From Attix, F. H., et. al., RADIATION DOSIMETRY, Vol. II, 1966. Courtesy of Academic Press, New York). The arrow A shows a thermoluminescent powder (or disc) being heated by filament B. As the temperature increases, the thermoluminescent material emits light (see glow curves of Figure 11), which passes through filters C and D and produces current in the photomultiplier tube.

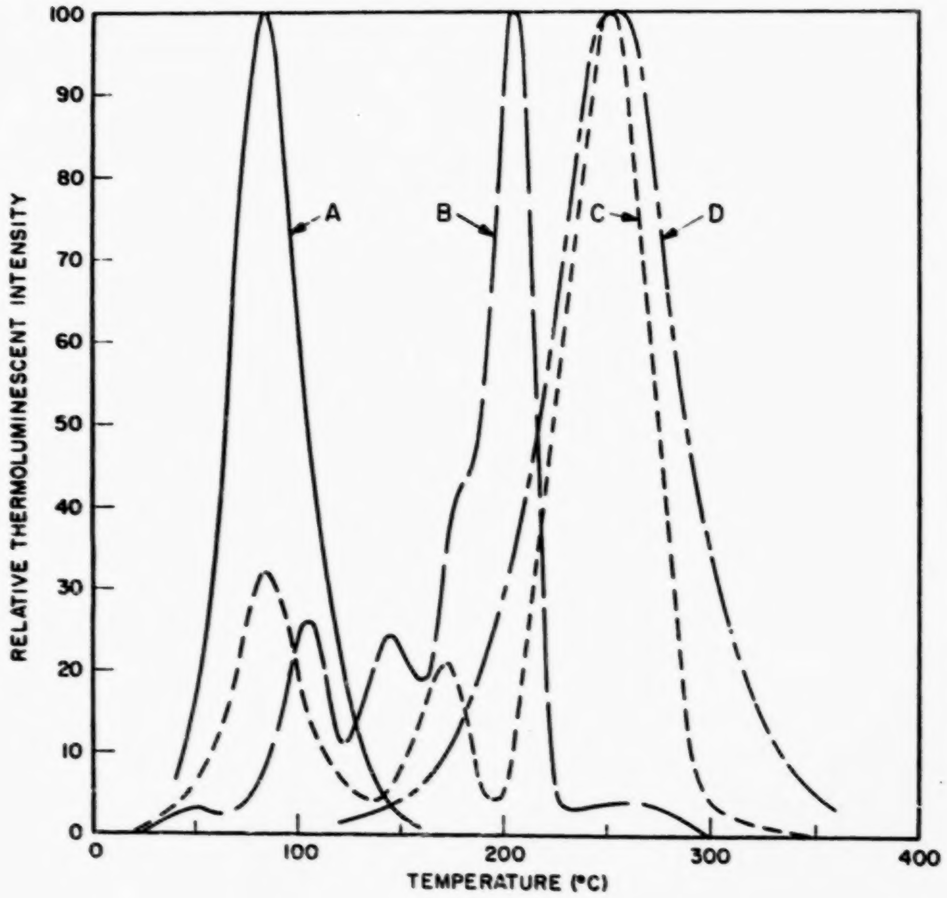

Figure 11
Sample Glow Curves as Readout Temperature is Increased for Thermoluminescent Dosimeters. The peaks as well as the areas of these curves are generally proportional to the radiation dose received by a particular thermoluminescent material. (From Attix, F. H., et. al., RADIATION DOSIMETRY, Vol. II, 1966 Courtest of Academic Press, New York).

density, respectively. Thermoluminescent dosimeters may also be utilized in badges containing dosimeters placed between various types or thicknesses of filtration, in order to estimate exposures from several types or energies of radiation simultaneously.

Certain glasses that fluoresce under ultra-violet radiation after exposure to ionizing radiation have been utilized as personnel dosimeters (radiophotoluminescent dosimeters) but they have generally been used over a high dose range and have not been widely employed so far in monitoring routine occupational exposure. Silver phosphate glass dosimeters have been widely distributed to the armed forces for use in measuring exposures of about 50 roentgens or more in the event of nuclear war. Also, phosphate glass rods have been inserted into film badges in many atomic energy installations, for use in measuring exposures greater than about 25-50 r as an immediate supplementary measurement to the less sensitive film. The phosphate glass dosimeter may be conveniently readable over about 500-1000 r, where even the insensitive film in a routine monitoring packet would be so black that it would be difficult to read with an ordinary densitometer. Figure 12 shows a schematic diagram of a fluorimeter for measuring phosphate glass dosimeters.

A number of other techniques are available for measuring ionizing radiation, and it may be expected that there will be further developments in personnel dosimeters in the future. Becker(24) has recently presented experimental data showing the potential usefulness in dosimetry of thin (1/100 cm) crystals that, when heated, emit electrons in proportion to the amount of ionizing radiation exposure previously received. These electrons may then be collected in the usual manner, or made to produce pulses within a Geiger counter to increase sensitivity. This phenomenon, called thermally stimulated electronic emission (TSEE), appears to be linear over a wide range of exposures.

Of course, none of the above instruments of personnel dosimetry generally meet the "Bragg-Gray conditions" for a primary measurement of dose and thus must be calibrated with suitable gamma-ray sources, or compared to secondary-standard laboratory instruments, such as the Victoreen "R chambers" shown in Figure 13. Each R chamber is designed to operate over a certain exposure range, and to respond in proportion to the roentgen exposure in air independently of photon energy over a wide photon-energy range. The R chambers are secondary standards, accurate to within about ±3 percent. They are calibrated in some known radiation field that has previously been standardized through the use of a standard air chamber, such as that illustrated schematically in Figure 1. However, for practical reasons, each type of personnel dosimeter is often designed for use in monitoring radiations outside the range over which it may "accurately" measure either the Roentgen exposure, or rad or rem dose.

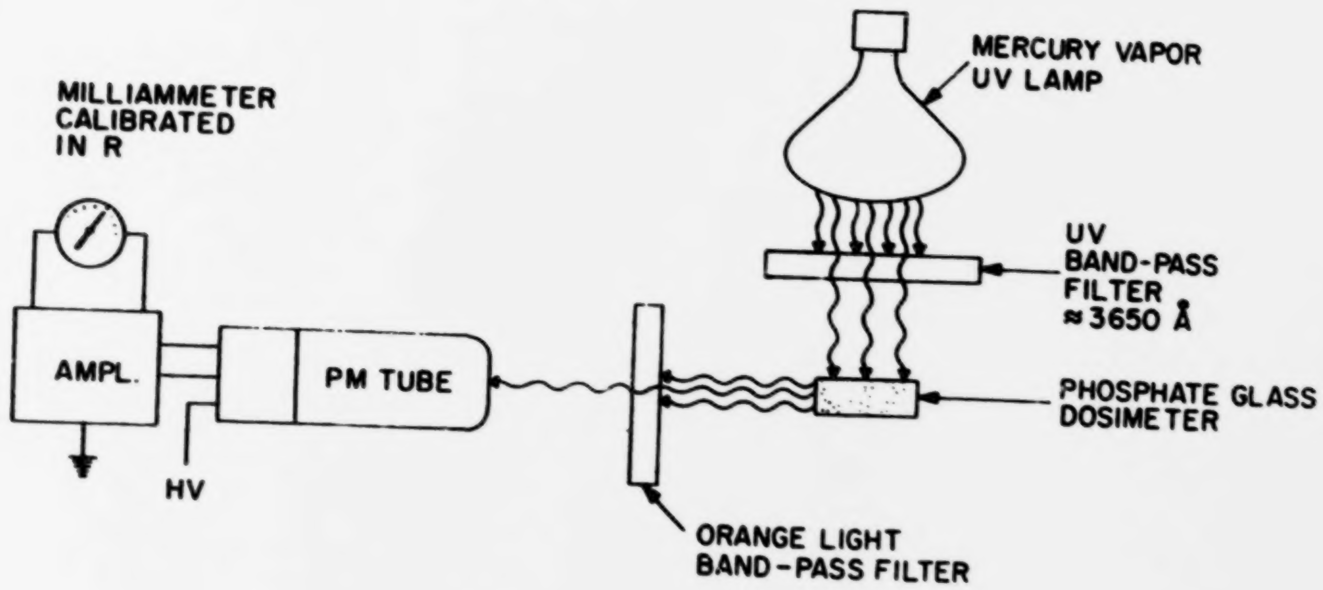
MILLIAMMETER CALIBRATED IN R
AMPL.
HV
PM TUBE
ORANGE LIGHT BAND-PASS FILTER
MERCURY VAPOR UV LAMP
UV BAND-PASS FILTER ≈3650 Å
PHOSPHATE GLASS DOSIMETER

Figure 12
Schematic Diagram of a Radioluminescent Glass Dosimeter System. (From Attix, F. H., et. al., RADIATION DOSIMETRY, Vol. II, 1966. Courtesy of Academic Press, New York).

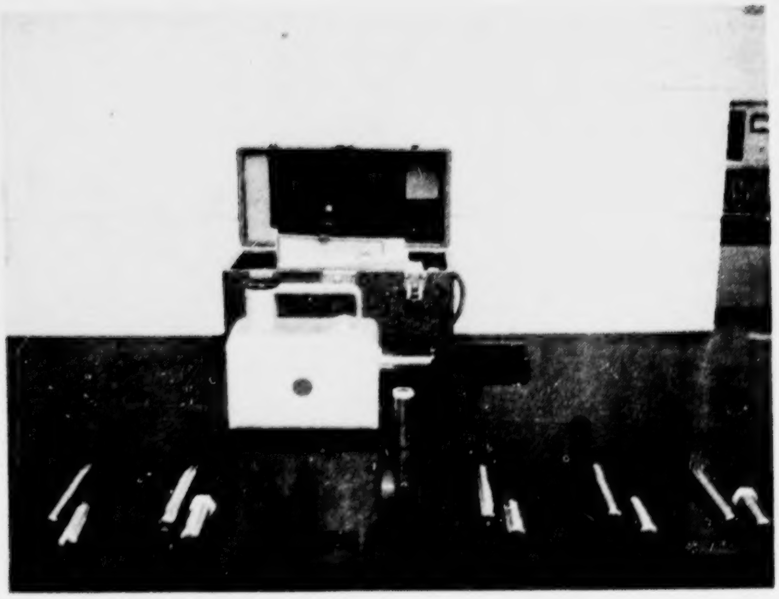

Figure 13

Photograph of a Set of Victoreen R-Chambers for Measuring Over Different Quantities and Energy Ranges of Gamma or X-Radiation. Also shown is an electrometer for reading and re-charging the chambers.

C. Portable Radiation Survey Instruments

Just as there are different types of personnel monitoring devices, there are many portable survey instruments for monitoring radiation intensities or exposure rates. Portable survey instruments are used to check the radiation intensities, or presence of radioactive contamination, in areas occupied or frequented by personnel. They supplement the use of personnel monitoring devices, and may either substitute for them or indicate the need for them. Atomic Energy Commission (AEC) regulations, Title 10, Code of Federal Regulations, Part 20(25) require AEC licensees to make periodic surveys of areas where licensed materials are used, and to provide personnel monitoring devices to employees in situations where they exceed, or may be likely to exceed, 25 percent of the maximum permissible quarterly dose limits (1 1/4 rem per quarter for whole body, lense of eye, gonad; 18 3/4 rem per quarter to hands and forearms, feet and ankles; 7 1/2 rem per quarter to the skin). Records must be maintained for periodic surveys in the same units as those specified in the regulations (i.e., R/hour for exposure rates, microcuries/cm^3 for concentrations of radioactive material in air and water). The National Council on Radiation Protection and Measurements (NCRP) has published many reports recommending appropriate equipment, facilities, and operating procedures, as well as radiation surveys for insuring protection from undue exposure to ionizing radiation.(26) The Federal regulations of several agencies have been based on these recommendations. Of particular interest to this conference is the recent NCRP publication(26) replacing the recommendations of National Bureau of Standards Handbook 76 with respect to the safe design and use of diagnostic and therapeutic x-ray and gamma-ray equipment.

Although the potential hazards of x-radiation were beginning to receive recognition early in this century,(27) portable survey instruments were not in wide use until the 1940's. Appropriate instruments for making radiation surveys became available commercially on a wide-scale following the Manhattan Project of World War II, when the design and construction of various types of portable survey instruments were given impetus by the expected large increase in radioactive materials produced by nuclear reactors. In recent years, the transistorized descendants of many of the types of instruments developed during and following the Manhattan Project have become widely used in medical installations as well as in nuclear industry. The variety of survey instruments for measuring radiation levels and concentrations of radioactive material in the employee and public environment is too great to allow an adequate description or classification in this paper. Many of the texts cited in the references(1-26) discuss the construction and operation of survey meters. Price(28) presents a discussion of the electronic circuits of these instruments. The following paragraphs will illustrate the principles of operation of some typical portable survey meters.

Figure 14 shows some typical survey instruments, from the Radiation

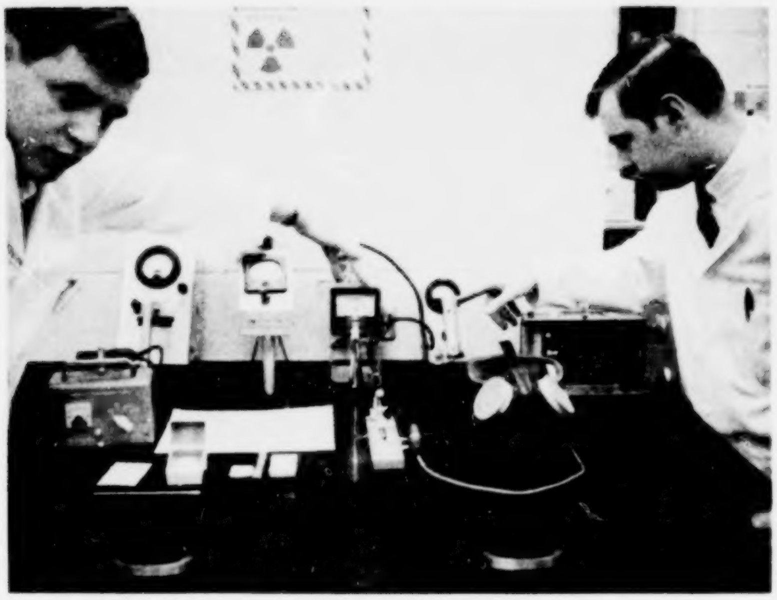

Figure 14

Photograph illustrating the variety of types of portable equipment used in routine radiation monitoring at the University of Pittsburgh, Radiation Safety Office. Back row, left to right: "Juno" ionization chamber survey meter; "Cutie Pie" ionization chamber survey meter; PAC-4G gas proportional alpha survey meter with probe; Geiger counter survey meter with GM probe; portable air sampler with filter head. Front row, left to right: laboratory monitor with probe; filter paper for taking smears; film packet, pocket chamber, and film badge for personnel monitoring; alpha probe of PAC-4G and GM probe of Geiger counter next to Pu-239 alpha source; face mask for limited work in high airborne concentrations of radioactive material. The man on the left is pointing to the alpha count-rate on the PAC-4G; the GM counter wall in this case is too thick for alpha penetration, so the GM indicates only a small count-rate due to environmental gamma and cosmic radiation.

Safety Office, University of Pittsburgh. The "Juno" survey meter is an ionization chamber(28) instrument operated on batteries; it can measure gamma radiation intensities over about the 0.001 to 5 R/hour range. An ionization-chamber instrument operates with sufficient voltage that it collects all of the ions produced in the ionization chamber by the radiation field. Either the flow-rate of the ions into the collecting electrode is measured as a current proportional to the R/hr exposure rate, or the total charge may be accumulated over time in some instruments as a measure of the accumulated exposure in R. The Juno is an exposure-rate measuring device for x or gamma radiation fields. However, to make the instruments more generally useful in survey work, two sliding windows have been added at the bottom of the chamber. These windows will allow the penetration of beta rays and alpha particles, respectively, so the instrument may be used to check laboratory surfaces for contamination by alpha or beta emitters that could be hazardous if taken into the body.

Although the Juno can measure most contaminants at hazardous levels, more sensitive instruments, such as alpha proportional counters, open-window Geiger-Mueller (GM) counters, and alpha scintillation counters are available to detect lower levels of contamination before they become a serious problem, or as an indication of possible air-borne activity that could result from, or cause, loose surface contamination.

Ion chamber instruments with large open windows, such as the Juno, may also be used to measure the Roentgen exposure rate from scattered x-rays in medical installations. These large portable ion chambers do not quite satisfy the Bragg-Gray principle for, say, 20-60 kev photon fields. However, when the open window of the instrument is held toward the radiation source, there is usually enough air between the source and the ion chamber to act as an "air wall", creating a nearly equilibrium flux density of recoil electrons flowing into and through the chamber. Thus, the ionization rate in the air within the chamber becomes proportional to the air exposure rate in Roentgens/hour, fairly independent of the radiation quality, or energy per individual gamma photon. Instruments similar to the Juno have recently become available that are designed to monitor x-ray exposure rates within about 5% accuracy over the entire range of diagnostic and therapeutic x-ray photon energies.

Proportional counters and GM counters, as mentioned above, are two other well-known types of radiation survey instruments utilizing the principle of air or gas ionization. Higher voltages in the proportional counter, combined with special gases allowing appropriate ion mobility and protection from environmental changes, will allow electron avalanching as the electrons from ionized atoms rush to the collecting electrode. These avalanches produce electrical pulses that are large enough to allow individual measurement of each quantum of radiation that interacts with the detector. These pulses may be integrated and measured as current with an ammeter, or may be amplified as individual pulses to actuate clicks or "pops" in an earphone or speaker, allowing the most sensitive detection of low-level contamination. If the voltage on the counter is in an appropriate region, the pulses will be proportional to the amounts of charge released in the chamber by the ionizing particles. Thus, electronic bias can be used to record alpha particle pulses without the background noise of the smaller pulses from beta particles or secondary electrons produced by gamma or x-rays. In this way, counters are constructed that discriminate between different types of radiation for specific purposes.

Neutron survey meters also utilize the proportional-counting principle in order to allow measurements of neutron exposure in the presence of considerable intensities of gamma radiation. Fast neutrons are usually detected by their collisions with hydrogen atoms in the counter inner chamber that traverse the counter gas and produce an ionization pulse in the proportional counter that is many times the size of any ambient pulses produced by electron recoils from gamma rays. By appropriate design of the counter walls and gas, and appropriate electron pulse discrimination, detectors have thus been produced that give readings proportional to the "first-collision" tissue dose from hydrogen atoms recoiled by fast neutrons, in the 1-15 Mev range, that would recoil and produce ionization in the body in a similar way as in the counter.(29) It must be noted, however, that these types of proportional counters can be made insensitive to gamma radiation only up to a limited intensity, and this intensity may be rather low when measuring radiations from a pulsed accelerator or nuclear reactor. However, the response of any detector to pulse "pile-up" from the arrival and interaction of many gamma rays at once may be predicted, and it usually turns out that a neutron counter that responds linearly with source intensity is reading properly.(30,31) When in error at all, exposures measured with neutron counters will probably be interpreted on the high side, since energy absorption from neutrons is assigned a relative biological effectiveness of 10. Even pulses produced by multiple gamma rays that are assumed to be neutrons are likely to be over-assigned in estimating dose-rates.

Another type of proportional counter used to measure neutrons is the "long-counter." This counter contains a boron-lined counting tube with boron-trifluoride (BF_3) gas, surrounded by a cylindrical sheath of hydrogenous material that "slows down" the fast neutrons by providing about 15 or more collisions with hydrogen atoms by the time they reach the detecting tube. The sheath also transmits sufficient slow neutrons so that the detecting tube measures over a broad range of neutron energies. This detector, however, provides a count-rate proportional to the number of neutrons incident upon the detector, independent of their individual energies. Thus, the count-rate must be converted to dose-rate in rem/hour from additional knowledge of the neutron energy spectrum and the relative biological effectiveness (or quality) factors as a function of energy.(32,33,34) A general discussion of neutron detectors is presented in Reference 35.

As the voltage across an ionization detector is raised further, a plateau in response is reached called the "Geiger" region,(28) used in GM counters. At this point, all pulses are about the same order of magnitude regardless of the nature of the particles that originated them. (The original ionization produced by the radiation quantum may be amplified by as much as a factor of one million by the avalanche within the GM tube). Although there is no longer a possibility of discriminating between alpha and beta produced pulses with these detectors (they are not generally used for neutron detection), these GM counters are widely used for their sensitivity, simplicity, rugged construction, and economy, for general survey purposes where detection of radioactivity is desired. They may also be calibrated to provide an estimate of external x- or gamma radiation exposure levels in Roentgens/hour (R/hour) or milliroentgens per hour (mR/hour). They are sensitive enough so that ordinary background radiation of 0.02 mR/hour provides a measurable scale reading of about 50 clicks per minute in the earphones of an average size GM tube.

In Figure 14, the survey meter next to the right end in the back row is a GM counter. The probe is next to a Pu-239 alpha source emitting about 50,000 alpha particles per minute and parallel to the probe of an Eberline PAC-4G alpha proportional counter, sitting to the left of the GM counter in the back row. Although the probe of the particular GM counter of figure 14 has a glass wall that is too thick to admit alpha particles, we see that the needle on the meter gives a slight reading greater than zero due just to background gamma radiation. This serves as a "built-in" check that the instrument is operating. The PAC-4G alpha counter can be seen to be responding to the alpha particles, since the bottom face of the chamber is covered with an extremely thin (but reinforced) material. The alpha counter would read zero if the alpha source were moved just a few centimeters away, the range of the alpha particles in air.

Other typical survey equipment shown in Figure 14 includes an air sampler with pump to collect a sample of air dust particles to check for airborne radioactivity, and (left to right, front row): a small laboratory area monitor with GM probe on top; filter papers for smearing surfaces to check for loose contamination; a film packet, pocket chamber, and film badge for personnel monitoring; and a full face mask used when entering areas where the potential for airborne radioactivity is high. Figure 15 illustrates some health physics laboratory equipment.

Many other types of radiation monitoring instruments are available.(36,37) The above descriptions of some of the more frequently used instruments may serve to illustrate the complexity of the problem of monitoring for the many different types of radiation. Thus, an accuracy of ± 25 percent is readily accepted for purposes of monitoring

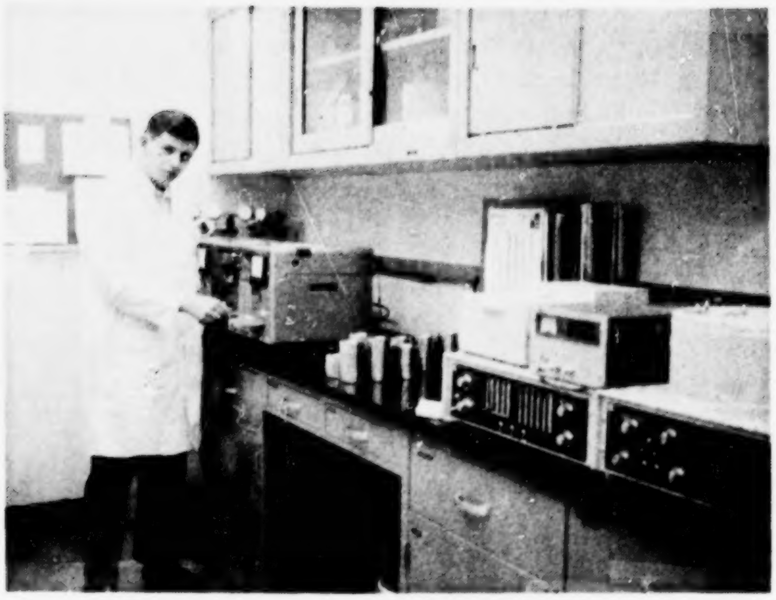

Figure 15

Photograph of laboratory counting equipment. A health physicist in the Radiation Safety Office is inserting a smear sample taken in another laboratory into an internal gas proportional counter, in order to obtain the most sensitive indication of the presence or absence of removable radioactive contamination.

exposure rates, and sometimes even a factor of two or three is satisfactory, in order to minimize the number and/or expense of the instruments the radiological or health physicist must carry in the field. In any event, individual biological response to a given exposure may vary by a factor of 2-3. The expected magnitude or frequency of any particular long-term biological response (e.g., carcinogenesis) is extremely low and also uncertain when personnel exposure are kept below the recommended average of 5 Rem per year.* Thus, it is usually simpler to provide additional protection in the nature of equipment or procedures when safety situations are borderline, than concern oneself about achieving more accurate estimates of individual personnel exposures. A single additional safeguard or procedure (e.g., a lead apron, different operating position, use of a glovebox, instead of a chemical hood) will often provide orders of magnitude lower exposures in given work situations.(38) The selection(38) and design(39) of appropriate facilities, equipment, and procedures for minimizing radiation exposure is a broad subject in itself and beyond the scope of this conference.

IV. ASSESSMENT OF INTERNALLY DEPOSITED RADIONUCLIDES

The prediction or determination of the radiation doses in Rem received by internal organs of the body, as a result of the inhalation, ingestion, or injection of radioactive material into the body itself, must of course be done by indirect measurements and calculations. It is impractical and unnecessary to place dosimeters inside the body for radiation safety purposes to assess employee exposure. Certain medical purposes may warrant the use of TLD dosimeters, Sievert chambers, or other small dosimeters inside the body to check for prognostic purposes the therapeutic doses administered to patients by implants or radioactive drugs. Although suggestions(40) have been made for recording patient exposure, NCRP recommendations(26) and Federal regulations(25) do not require the routine measurement of internal or external exposure to patients, nor maintenance of records of such measurements. The calculations and observations of the radiologists are at present assumed sufficiently precise to insure a proper balancing of benefit and risk for the individual patient. Nevertheless, the Surgeon General of the Public Health Service has cautioned that all radiation exposure is believed to involve an element of risk, and thus the use of radiation in medical procedures should reduce any "unproductive radiation exposure."(41) Most of the genetically significant dose from medical procedures to the United States population (about 55 mr per year)(42) is believed to be a result of radiography examinations(41) involving external irradiation.

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*The average incidence rate for leukemia in Hiroshima and Nagasaki survivors indicated a probability of leukemia, for example, of only 1-2 cases per year per million population per rem of exposure. A considerable portion of this was gamma radiation. Considering that more than 1 billion photons pass through each square centimeter cross section of the body for 1 R of exposure (see Table 1), we can see that the induction of leukemia by sub-lethal radiation exposures is an extremely rare event, subject to the laws of chance and their uncertainties.

Exposure from internal radioactivity is minimized by monitoring and controlling the intake of radioactive materials. Many different types of portable or semi-portable samplers that collect particulates from the atmosphere for radioactivity and particle size analysis are available.(39) These air samplers, preferably used at the breathing zones of the worker,(43) are, for assessing potential internal exposure from inhaled radionuclides, the counterpart to the portable survey meters for assessing potential irradiation by external radiation sources. Similar sampling of water and food sources is carried out to monitor the ingestion of radioactive materials. Concentrations of radioactive materials in air and water (or food) are then compared with "maximum permissible concentrations" (MPC's) recommended by the International Committee on Radiation Protection (ICRP) and the NCRP,(3,44) or single intakes of the respective radionuclides that will result in the recommended dose limits for respective body organs.(45,38) The maximum permissible concentrations for occupational exposure are selected by calculating the concentrations in air, or water, so that the equilibrium rate of intake is equal to the rate of removal of radioactivity from the critical organ when a "maximum permissible" organ burden (maximum permissible body burden times fraction in organ)(3) is built up in the body; or for long-lived nuclides with low biological turnover, when the quantity of radioactivity in the "critical organ" would build up to the maximum permissible organ burden after 50 years of exposure to the maximum permissible concentration in air. The reader should refer to the basic derivation of MPC's and the physical and biological literature presented by the ICRP in their 1959(3) and subsequent recommendations. More refined calculations of organ dose may be made in specific circumstances, when warranted, with the geometrical correction factors recently published by the Society of Nuclear Medicine.(46) The MPC's published by the ICRP(3) have been generally adapted in regulations of the AEC,(25) Labor Department, and many states.

For a more direct determination of individual exposure from internal emitters, the analysis of radioactivity in breath or excreta, and in vivo counting for gamma or bremsstrahlung emitters, is the counterpart of personnel monitoring for external radiation. The study of techniques for inferring internal organ exposures from excretion measurements or whole body counting has become itself a sub-profession of the field of radiation protection. Each year an informal bioassay conference is held for several hundred invitees to discuss the latest methods of internal exposure evaluation.(47) The subject of these conferences is called "bioassay" of radioactive materials in the human body. The term "bioassay" here has a different connotation than that normally used in toxicology or pharmacology.

It was in fact chosen during the Manhattan project as a code word to confuse the nature of the activity being carried on. When used in the field of radiation protection, "bioassay" simply means the estimation of internal radiation exposure from radioactive materials taken into the body by analysis of excreta, breath samples, or externally-measured gamma- or x-rays emitted from the body (whole body counting).

A considerable amount of literature(48-52) is available on the methods for analyzing radioactivity in biological samples. The interpretation of organ burdens may be done using available animal and human data in the literature on particular radionuclides, and compilations of biological rates of turnover of radioactive material in various organs.(3,53) A number of publications of methods of whole body counting are available.(57-58) Table 2 shows the sensitivity of an 8"Dx4" NaI crystal placed behind the lower back for determining some of the radionuclides encountered at the University of Pittsburgh whole body counter.(59) Table 2 also includes some sensitivities for the more difficult nuclides to measure, such as Pu-239, measured with a 2"Dx1mm crystal.(84) The accuracy of these measurements at levels above detection limits is often accepted to be no better than a factor of 2 for routine radiation control purposes at levels below maximum permissible body burdens.

The detection limits for in vivo scintillation counting are lower than the maximum permissible body burden for almost all nuclides, except for certain alpha-emitting isotopes of thorium, uranium and the transuranium elements. A few special, low-energy, beta emitters such as tritium and Carbon-14 also cannot be measured by external counting, but must be evaluated from measurements of their concentrations in urine, feces or breath. However, in the case of the frequently-used tritium and C-14 compounds, the radioactivity is frequently distributed rapidly throughout the body, and is soon in equilibrium with excreta in sufficient concentrations for easy detection when body burdens are still only a small fraction of the maximum permissible levels.(3,47,48) Special consideration must be given, however, to the incorporation of tritium and C-14 into complex organic molecules, particularly those nucleotide precursors that may incorporate into DNA and bombard the genetic materials at close range. The hazard of such compounds may be 100 to 1000 times that of ordinary tritium oxide or C-14 dioxide.

Excretion measurements are also a necessary supplement, and sometimes the primary sources of data, for evaluation of body burdens of the more radiotoxic transuranium elements such as Pu-239 and Am-241. Natural uranium also is difficult to measure by external counting techniques, but does show up in the urine except for extremely insoluble oxides inhaled into the lung. The isotopes of polonium, iodine, mercury, strontium, calcium, radium, iron, sodium, cesium and many others are often subject to urinalysis. Isotopes of elements

Table 2

Sensitivities of University of Pittsburgh Procedures for Several Nuclides

Radionuclide	Lower (97.5% CL) Limit of Detection in Lung for 40 Minutes with Standard Chair Technique	Maximum Permissible Body Burden(1)	Fraction of MPBB Detectable
Fission products:			
Cs-137	2×10^{-4} µCi	30 µCi	6.6×10^{-6}
Zr-95-Nb-95	9×10^{-5} µCi	20 µCi	4.5×10^{-6}
I-131	3×10^{-4} µCi	0.7µCi	4.3×10^{-4}
Ba-140-La-140	9×10^{-4} µCi	4 µCi	2.2×10^{-4}
Ce-144-Pr-144	2×10^{-3} µCi	5 µCi	4.0×10^{-4}
Co-60	4×10^{-4} µCi	10 µCi	4.0×10^{-5}
Uranium-238(3)	4×10^{-4} µCi	5×10^{-3} µCi	0.08
Uranium-235	1×10^{-4} µCi	0.03 µCi	0.003
Thorium-Natural(2)	6×10^{-4} µCi	0.04 µCi	0.015
Plutonium-239(3)	0.03 µCi	0.04 µCi	0.75
Americium-241(3)	4×10^{-4} µCi	0.05 µCi	0.008*
Natural Potassium	Measurable within ± 3% for adult males		
Total Gamma Activity (Equivalent)	6×10^{-4} (Cs-137 equivalent)		

(1) As given in ICRP Committee II Report, Health Physics 3, 1960, for the total body burden when the most critical organ is receiving the maximum permissible occupational exposure rate.

(2) Evaluated by a procedure similar to that given by L. M. Scott, Health Physics 12, 101-102, January, 1966.

(3) Counted with a thin-window, 1 mm thick x 2"D NaI crystal against chest for 40 minutes, to detect low energy photons, as in Reference 84.

*≤ 0.0033 µCi for 10 minute count on 8x4 behind back, assuming ±25% fluctuation for uncertainty of K-40 background.

such as thorium and the rare earths often require fecal analysis even when taken into the body in forms soluble in water. However, the frequent necessity for fecal analyses for various inhaled compounds that are insoluble in lung fluids has been emphasized more and more in recent years.(60,61)

Mathematical models relating fecal and urinalysis to internal body burdens of radioactive materials have been developed.(62-68) In references 64-66, the more recent ICRP lung model(53) has been incorporated into the analyses. The evaluation of body burdens from extremely radiotoxic nuclides(3,38) such as plutonium and americium may be enhanced by administration of test doses of the chelating agent DTPA (diethylene-triamine-pentaacetic acid), which will increase excretion rates by factors of 10 or more for these radioelements and allow their detection at systemic levels below their respective maximum permissible body burdens.(69)

Although individual daily excretion samples are subject to considerable variability in radioisotope concentrations, many samples taken over periods of months or years can often provide assessments of the internal radiation exposure of a body organ to within a factor of 3. When the uncertainty in the estimate causes the upper estimates to exceed regulatory exposure limits, we sometimes find ourselves in unresolved legal questions of violation of regulations, even though the significance of the exposure may be questionable in consideration of the safety factors included in the maximum permissible levels and the uncertain nature of dose-response relationships at low dose levels, and uncertain individual biological variations. Perhaps this conference can include a consideration of the legal questions involved in dealing with the stochastic variations in dose and biological response, as well as the uncertain and probabilistic nature of the underlying dose-response relationships.

V. ACCURACY AND SENSITIVITY OF MEASUREMENTS

Some mention of acceptable ranges of accuracy has been included to provide perspective in preceding sections of this paper. However, in view of the considerable discussion of questions of accuracy and validity of radiation monitoring records in recent years, I would like to introduce a few specific points for further consideration. Many of the basic questions concerning the degree of accuracy and sensitivity required in radiation monitoring, for legal as well as operational safety purposes, have still not been resolved to the satisfaction of all professionals concerned. Perhaps it is just such conferences as this, with the legal, radiological, and health physics professions working together, that will begin to solve or obtain agreement on the basic questions(70) of: what accuracy, and what records, are required for litigation purposes?

Several attempts have been made over the years to define acceptable levels of accuracy and precision for personnel monitoring services,(71-73) in the absence of any quantitatively defined requirements for litigation purposes. These attempts generally resulted in the formulation of tentative performance requirements, to be tested for individual personnel monitoring services by requiring the interpretation of laboratory-exposed dosimeters. In this way, it was hoped that personnel monitoring services submitting themselves to such tests would ultimately improve quality control and accuracy of dose interpretations. The National Sanitation Foundation now operates a testing service to which most commercial film badge services subscribe. The NSF performance criteria(72) specify the frequency of interpretations of exposure that must lie within given accuracy limits for various quantities and types of radiation. These limits are not inconsistent with the general order of magnitude of those previously proposed by the AEC.(71) Many of the same individuals were consulted in the development of both sets of criteria.

Despite this apparent approach to general agreement on performance criteria for radiation control purposes, some questions still remain regarding methods of quality control testing and accuracy and recording requirements for records needed in litigation(74) (not to mention radiation control purposes, and purposes of epidemiological investigations of effects of low-level population exposure.)(75,76) I believe that we must go back to answering certain more basic questions concerning the fundamental variability of dose measurements and biological response. The legal profession must also recognize the probabilistic and uncertain nature of low-level radiation effects. We should already be aware of the fact that the long latent periods between exposure and manifestation of disease, and the impossibility of relating a purely long-term injury or effect with certainty to the initiating agent (either radiation exposure or some other chemical or viral agent that may produce the same disease), preclude the establishment of cause-effect relationships in any individual case with a reasonable degree of certainty, even for exposure to many Roentgens of radiation.

Much of the frustration in dealing with this complex problem has been blamed on the errors in personnel monitoring. As a result, these errors have often been overstated, and traced to the wrong causes. Time does not allow me to deal with this question in detail, but I should like to present a few facts about the accuracy and precision attainable in personnel dosimetry.

Errors in dosimetry may be classified into two categories:(20,73)

(1) Errors intrinsic to the physical detection system itself--resulting from random noise or fluctuations in fog density of films, ripple in the laying of thin photographic emulsions onto a plastic strip, thermal noise in detectors or amplifiers in the case of survey instruments, etc.; and,

(2) Extrinsic errors--produced by factors or methods of interpretation that are stochastically independent of the particular

physical or chemical measuring system itself, such as the use of an inaccurate value for the activity of the calibration source (a "fixed" error for a particular service laboratory), the wearing of the dosimeter at a part of the body other than that receiving the highest proportion of its permissible exposure (may vary randomly between individuals, etc.), or a system of dose interpretation that is inaccurate for the particular radiation at hand.

A linear mathematical model of these errors has been proposed,(73) assuming that the overall error can be represented by a constant fixed error (bias) plus a randomly fluctuating (plus and minus) error. However, there is some evidence that errors in dosimetry, as well as the dose distributions between individuals themselves, are multiplicative in nature and often the error is represented by a stochastic factor that is log-normally distributed with some geometrical standard deviation about a given median value (the bias). An understanding and consideration of the log-normal nature of many extrinsic and intrinsic errors in dosimetry may ultimately lead to a better appreciation of these errors and the development of appropriate methods of dose recording and quality control.

A number of studies have attempted to define the general magnitudes of errors in personnel dosimetry.(20,21,22,72,73,77,16) Figure 16 shows a plot,(78) on log-probability paper of the cumulative distributions of ratios Y_i/X_i, of reported divided by delivered doses, for those film badges of each radiation category that were next to farthest away from perfect performance, for each of 26 companies tested by the National Sanitation Foundation in 1965.(72) These distributions were plotted in order to study the nature of the overall errors in film dosimetry. When these same points were plotted on a linear-probability paper, they lay on a curve rather than a straight line, showing that a log-normal frequency distribution would be a better description of the data. Figure 16 shows the frequency distribution of error factors for the data pooled for all categories in order to obtain a sufficient sample size for a gross picture of the distribution of errors, without considering any particular weighting of different radiation categories. This approximate fit to a log-normal distribution of errors supported the selection by NSF of error bands that were equal distances on a logarithmic scale above and below the 45-degree line of perfect accuracy (i.e., error limits obtained by multiplying and dividing the median (true) dose value by the same error factor). As the performance of the companies improves, the slope of the line in Figure 16 should increase while the median moves closer to 1.

In Figure 16, the median is 0.88 (half the reported categories included Y_i/X_i values above 88% of the true dose and half reported below). The geometric standard deviation (Y_i/X_i at 50% divided by Y_i/X_i at 16%) is $s_g = 1.72$, meaning that 68 percent of the Y_i/X_i values

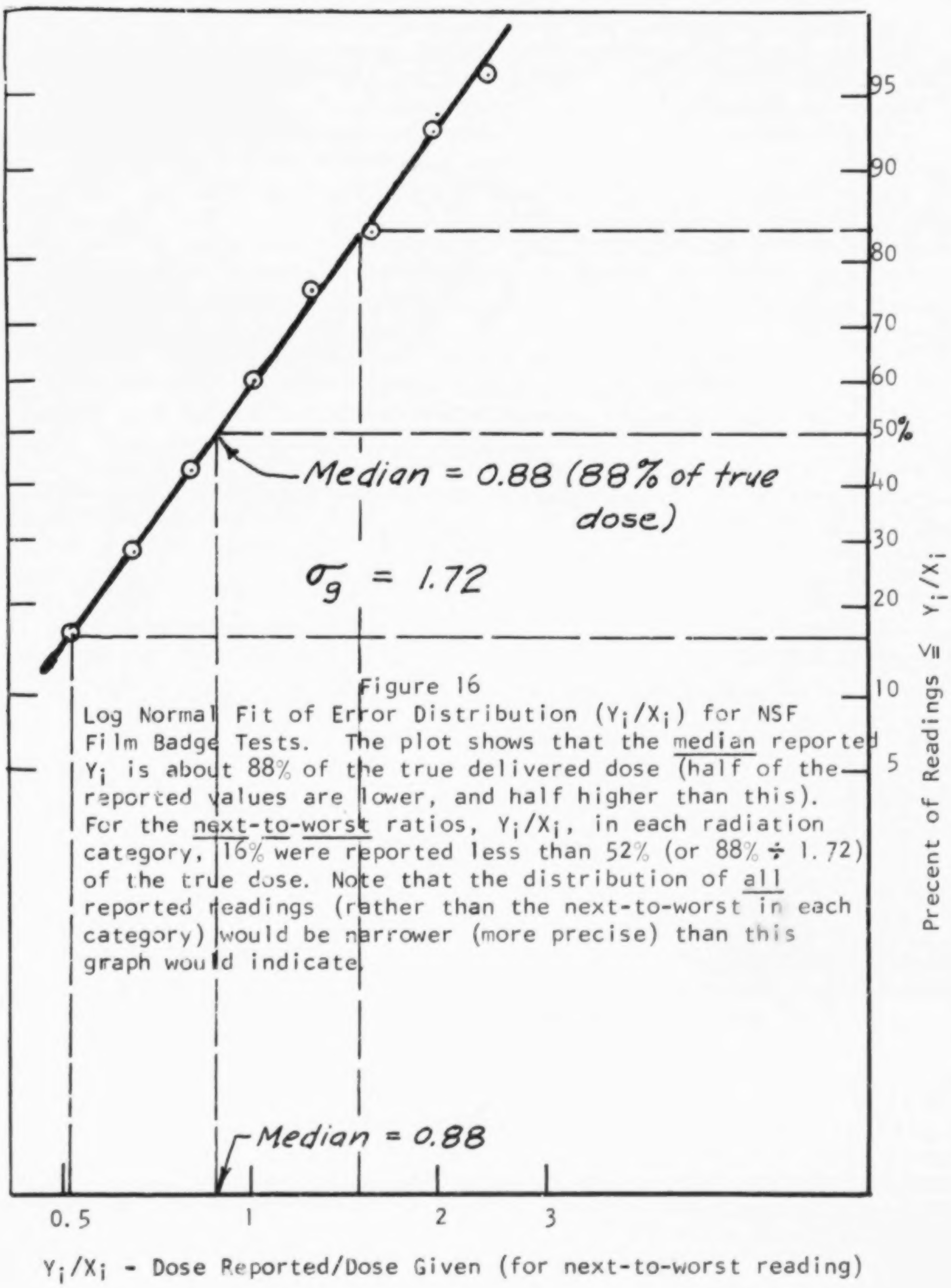


Figure 16

Log Normal Fit of Error Distribution (Y_i/X_i) for NSF Film Badge Tests. The plot shows that the median reported Y_i is about 88% of the true delivered dose (half of the reported values are lower, and half higher than this). For the next-to-worst ratios, Y_i/X_i, in each radiation category, 16% were reported less than 52% (or 88% ÷ 1.72) of the true dose. Note that the distribution of all reported readings (rather than the next-to-worst in each category) would be narrower (more precise) than this graph would indicate.

lie between (88 x 1.72)% and (88/1.72)% of the true dose; and about 95% of the deviations lie between $88 \times (1.72)^2\%$ and $88/(1.72)^2\%$ of the true dose; i.e., within a "factor of 3" of the true dose.

In order to determine the feasibility of improving film badge performance, studies were carried out on the magnitudes and causes of both intrinsic and extrinsic errors in film dosimetry,(20,21,75) including studies of the agreement between population exposures in the nuclear industry from film badges compared to exposures recorded from pocket chambers, when both instruments were utilized fairly regularly.(75) The results of these studies are too numerous and complex to report here, but I would like to show certain fundamental findings of interest.

Table 3 shows the variability of individual interpretations from badges exposed weekly to 10 mr from a radium-gamma source, for different environmental conditions representing some of the more extreme environments encountered in the field. In Table 3 we can note the powerful effect of the statistical law of large numbers showing that when even small and variable measurements are recorded as obtained to within appropriate significant digits, the random variations will tend to cancel over a 12 week period, for each of the environmental conditions, to give a total dose within 10% of the true total 120 mr dose. Similar results were obtained at other dose levels.(21) These results should indicate that when dose readings are recorded in an unbiased manner, film badges can measure as low as 10 mr of gamma radiation and much lower amounts of x-radiation with sufficient precision for general personnel monitoring purposes, particularly if the films or other sensing devices are protected from any environmental effects by suitable wrappers. Further interpretations(79) of the results of these experiments, together with microscopic examinations of film emulsions and studies with optical density amplification(80) showed that the sensitivity of films may be limited primarily by fluctuations of only a few percent in film emulsion thickness or composition. Application of the law of large numbers in this study, and in subsequent investigations with the more sensitive Kodak Type 3 film, resulted in the curves of precision versus numbers-of-measurements shown in Figures 5 and 6, and the error bands shown in Figure 7. In Figure 7, we can see that the relatively constant width of the error band on a logarithmic scale over a range from about 10 mr to 1000 mr indicates a constant relative error (coefficient of variation) of about 11-12% resulting from intrinsic random errors for individual films exposed to gamma radiation. Figures 5 and 6 may also be used for time intervals other than one week if the weekly dose scale is replaced appropriately, and the number of films indicated for each precision curve is the same.

Thus, we may conclude, contrary to some previous expectations, that it is possible to obtain the same precision with a number of radiation dosimeters worn over a given period of time as with a cumulative reading on a single dosimeter, under ideal conditions and

Week ending	Individual net densities, and individual doses assigned from weekly calibration curves*											
	80°F 0% RH		80°F 24% RH		80°F 90% RH		100°F 0% RH		100°F 24% RH		100°F 85% RH	
	Net density	Assigned dose	Net density	Assigned dose	Net density	Assigned dose	Net density	Assigned dose	Net density	Assigned dose	Net density	Assigned dose
3/17/62	0.023	18.5	0.007	6.4	0.015	12.5	0.009	7.9	0.016	13.1		
3/24/62	0.020	11.6	0.017	9.6	0.017	9.6	0.015	8.4	0.008	4.3		
3/31/62	0.015	10.0	0.014	9.5	0.017	11.5	0.023	15.5	0.015	10.2		
4/7/62	0.012	9.6	0.013	10.4	0.014	11.2	0.024	18.8	0.020	15.7	0.008	6.5
4/14/62	0.009	5.3	0.014	9.0	0.013	8.2	0.010	6.1	0.017	11.2	0.020	13.5
4/21/62	0.008	7.4	0.017	14.0	0.017	14.0	0.014	11.8	0.013	9.9		
4/28/62	0.017	10.8	0.014	9.0	0.017	10.8	0.014	9.0	0.021	13.5		
5/5/62	0.014	7.9	0.012	6.7	0.012	6.7	0.015	8.6	0.017	9.8	0.018	10.4
5/12/62	0.016	4.9	0.028	9.8	0.011	3.0	0.012	3.4	0.015	4.5	0.020	6.4
5/19/62	0.022	14.3	0.015	9.3	0.010	6.4	0.008	5.2	0.011	7		
5/26/62	0.019	9.8	0.020	10.4	0.015	7.5	0.015	7.5	0.006	2.6		
6/2/62	0.014	7.9	0.013	7.2	0.008	4.3	0.017	9.8	0.017	9.8	0.016	9.1
Total		118.0		111.7		105.7		112		111.6		45.9
12-week Total dose assigned		118.0		111.7		105.7		112		111.6		$\frac{12}{5} \times 45.9 = 11$
Standard deviation		±2.8		±2.0		±3.2		±4.3		±4.0		±3.0
Pooled estimate of standard deviation of 12-week total = +12.3 mr (about 10.2%)												

* Note: A different calibration curve was plotted each week from the "calibration" films that were developed together with the rest of the week's films.

Table 3

Example, for weekly films, of relative magnitudes of single-film net densities, assigned doses, cumulative totals, standard deviations of individual dose assignments and standard deviations of 12-week totals (Reference 21); An experimental illustration of the power of the statistical law of large numbers in improving the accuracy of an average or sum calculated from many individual measurements.

with appropriate methods of recording. Moreover, under field conditions, with sensitivity as well as fading depending on temperature and humidity, the film badge worn for a longer period may in fact be even less accurate than a series of films each worn for a shorter period. This possibility is a result of the complex interactions of temperature, humidity and radiation effects on the photographic emulsion.(81)

Thus, we can see that the dosimeter itself should not be blamed for our problems. Moreover, even the most exact determination of dose (and exact precision is never obtainable for any measurement) will not eliminate all of our problems. Figure 17 shows typical S-shaped dose-response curves for lethality in animals. In Figure 18 similar curves for the irradiation of mice with both high-energy photons and x-rays have been plotted on a log-probability scale, showing the log-normal variations in the lethal dose required for animals of a given strain exposed to a given type of radiation.(82) We can see from these curves that as much as 5% of a population may vary by more than a factor of 2 from each other in their "sensitivities" to a given dose. Similar curves may be obtained for the induction of radiation carcinogenesis. In fact, it is often possible to explain much of this so-called biological variation, sometimes all of the variation for a given strain of animal, by the chance nature of the interactions of radiation with tissue.(83) This is seen when we note that for each roentgen of exposure, approximately a billion or more photons pass through each cm^2 cross-section of the body. We never find that suddenly above a given dose, all animals are affected, nor that below that dose, no animals are affected--for any type of repeatable radiobiological experiment in carcinogenesis, for example.

Thus, it is obvious that the induction of carcinogenesis by radiation at low dose levels is a random event, or sequence of random events. In fact, one may expect to observe the typical S-shaped log-normal dose-response curve even for only a particular 2-step mechanism of carcinogenesis,(83) just because it is less likely that a group of animals will survive without cancer as the radiation dose is increased. Since the probability of induction of neoplasms in man at low doses, although unknown, is known to be small, we can see that it is highly unlikely that any case of cancer many years after a low exposure can be traced to that exposure with any degree of certainty, even if the entire radiation dose history of the individual is known precisely for every point in tissue throughout his body. This is particularly true since the individual's possible exposures to other environmental agents that could cause the same diseases would still be indeterminate.

VI. SUMMARY

In summary, we can conclude only that radiation dosimetry and radiation biology are two very complex subjects. Hopefully, the

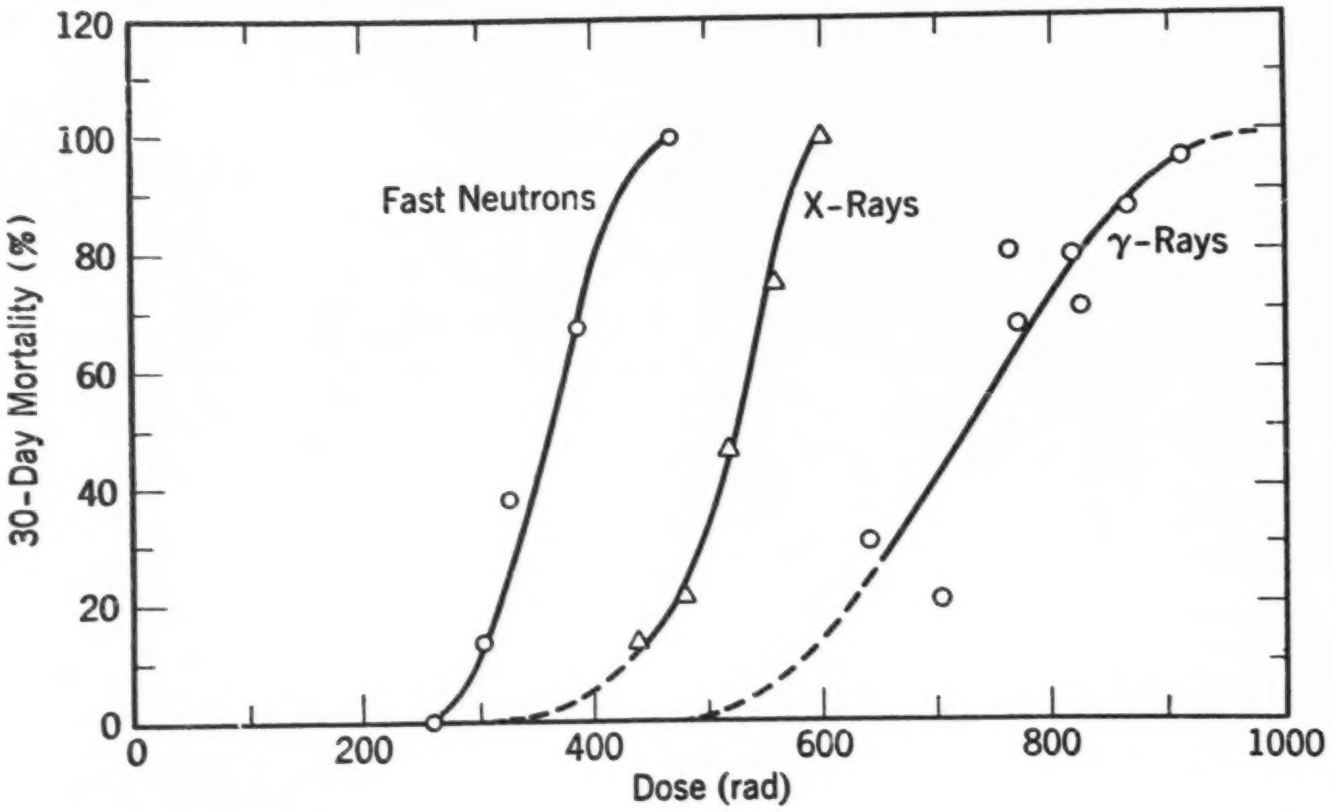


Figure 17
S-Shaped Dose Response Curves for 30-Day Mortality of Mice (From K. Z. Morgan, J. E. Turner, PRINCIPLES OF RADIATION PROTECTION--A Textbook of Health Physics, 1967, Courtesy of John Wiley and Sons, Inc., New York)

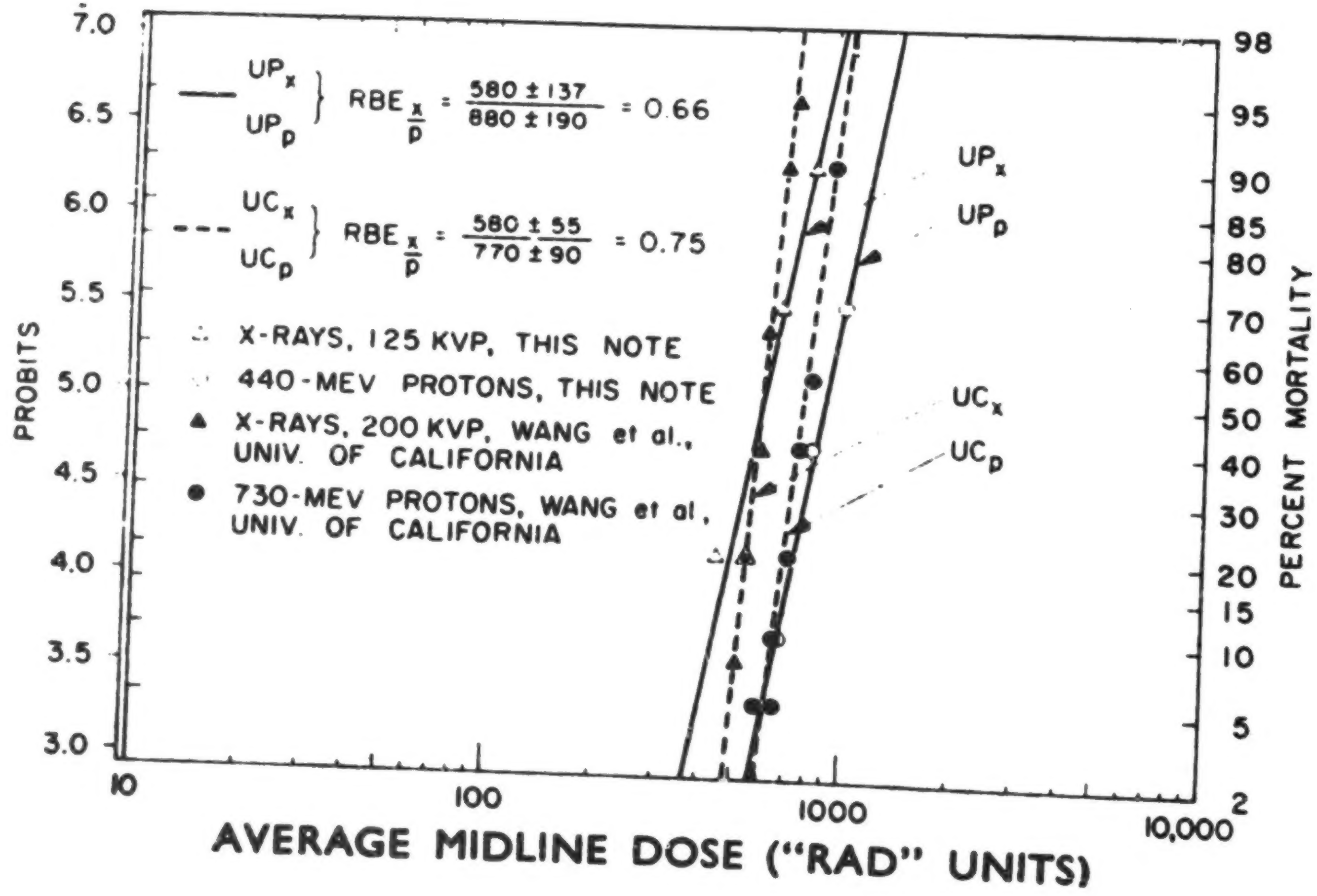


Figure 18
Probability Plot of S-Shaped Mortality Curves for Mice for Exposure to High Energy Protons and X-Rays, Showing the Log-Normal Distribution of the Data. (F. J. Bradley, et. al., Health Physics 10, p. 72, 1964. Courtesy of Pergamon Press, N. Y.)

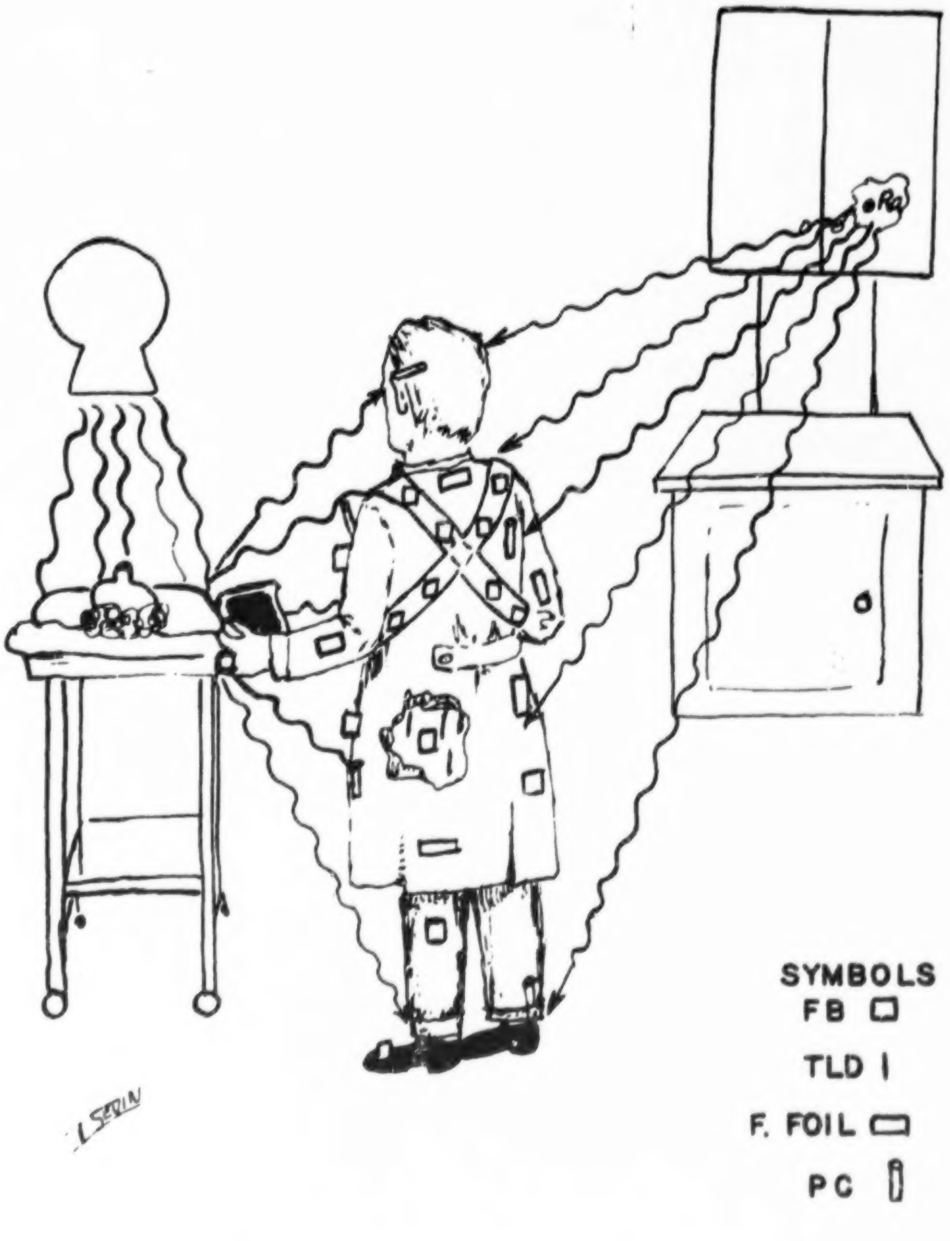
question of radiation record-keeping for litigation purposes will be somewhat less complex at the end of this conference.

Although the accuracy of radiation dosimeters has sometimes left something to be desired, radiation exposure has nevertheless been (in the atomic energy industry, at least) more completely measured and recorded than exposure to any other toxic agent of the environment. Measurements of radiation exposure can be made with sufficient precision for personnel monitoring and hazard control by any number of methods. The precision of film badge measurements was elaborated upon in this paper only as an example, because more experience with this type of dosimeter is available. No amount of precision in radiation dosimetry will serve litigation purposes, if these purposes include a requirement for the absolute verification of a causal relationship between exposure and long-term disease, because this relationship is at best"probabilistic."

Our general problems may be summarized visually in the following three pictures:

Figure 19 shows that only numerous radiation dosimeters placed all around and within the body can be expected to obtain a complete record of an individual's dose distribution, which Dr. Willhoit will explain is more pertinent than the dose at a single point of his body for predicting the extremely low probability of somatic effects at occupational exposure levels. At accident exposure levels, or therapeutic treatment levels, where immediate biological effects are observed, the probability of later consequences such as leukemia may still be less than 1 in 1000 even for several-hundred Roentgen exposures. Thus, is it really reasonable to attempt an exact determination of dose distribution for litigation purposes, unless there is also a medical need for the type of detailed therapeutic dose record to be discussed in later papers of this conference?

Figure 20 indicates that there is no such thing as a "biological dosimeter," nor a perfect dosimeter. My chemist, Miss I. F. Sevin, attempted in this picture to provide me with an exact replica sitting on my back to protect me from undue radiation exposure. However, even this gallant effort will not succeed. The exact twin specimen worn by the exposed Allen Brodsky holding the beaker is in fact shielded from the front, while Allen Brodsky is shielded by the "biological dosimeter" from behind. Even so, if the "dosimeter" sitting on his back were to develop leukemia 20 years later, or even chromosome anomalies 20 days after, one cannot say with certainty whether the biological effects on the replica were due to the radiation, or to the benzene evaporating from the flask. And even if the replica Allen Brodsky were affected, the real (?) Allen Brodsky might remain healthy as ever. Thus, the use of the word "dosimeter" must imply the use of an instrument that measures radiation dose uniquely, and independently of the biological effect with which the dose is to be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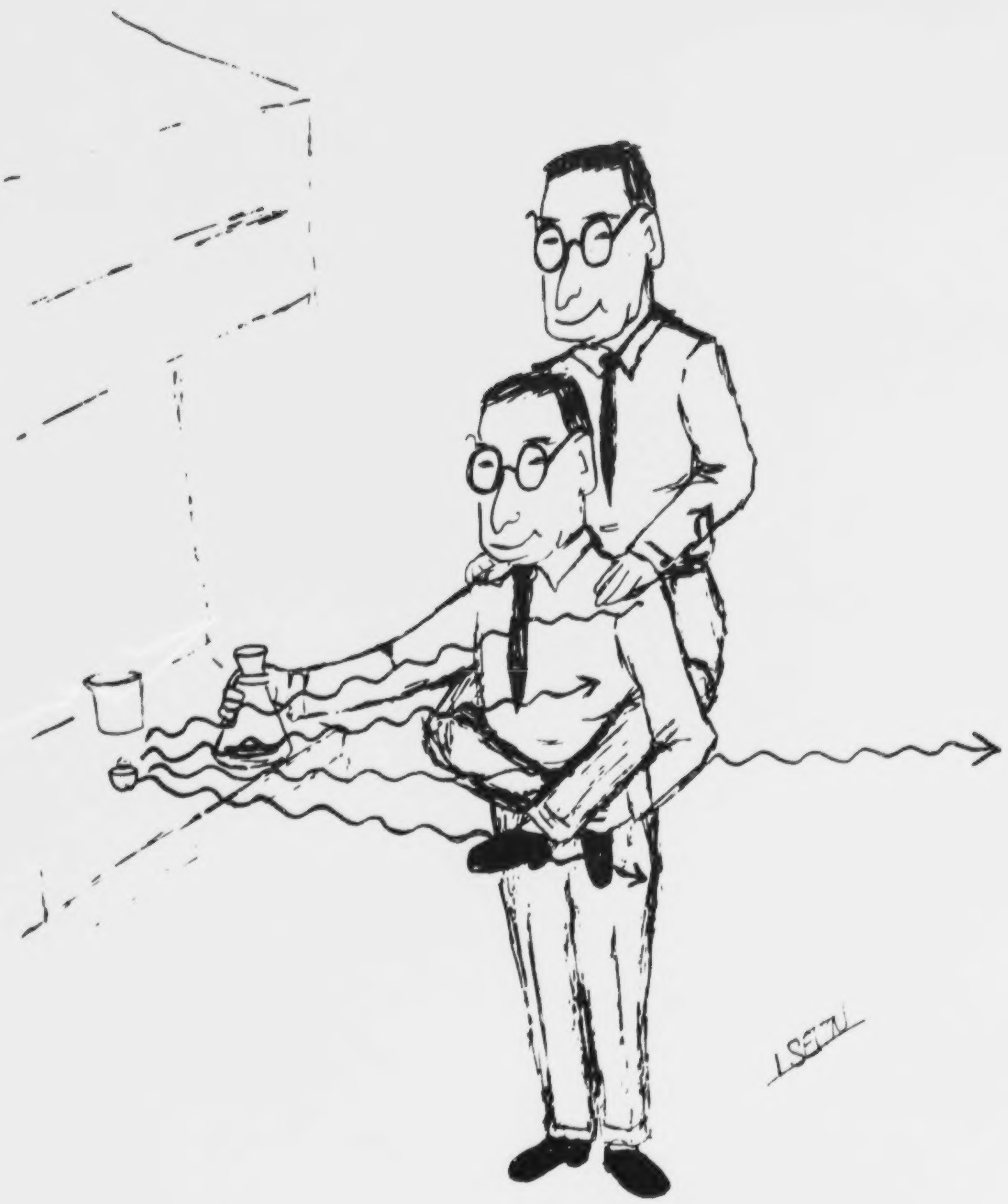
SYMBOLS
FB □
TLD |
F. FOIL ▭
PC ▯

DETERMINATION OF "WHOLE BODY" EXPOSURE

Figure 19



THE PERFECT(?) BIOLOGICAL(?) DOSIMETER(?)

Figure 20

correlated.

Finally, in Figure 21 we see the wide variation in biological response of different individuals, even above that which may be attributed to chance as mentioned in the previous paragraphs. Yet, we must remember that there are exposures so large that even the superman cannot survive; and so small that even the sick man will survive. Unfortunately, even the healthiest survivor will stubbornly retain that vanishingly small and troublesome, but yet not zero, probability of later effects. Perhaps this chance will be less than one chance in a million. Thus, we cannot say with absolute certainty he will never have a leukemia that resulted from his radiation exposure. Nor can we prove that radiation was the cause, nor one of the causes, if leukemia should in fact occur. I now leave you for the moment with this dilemma.

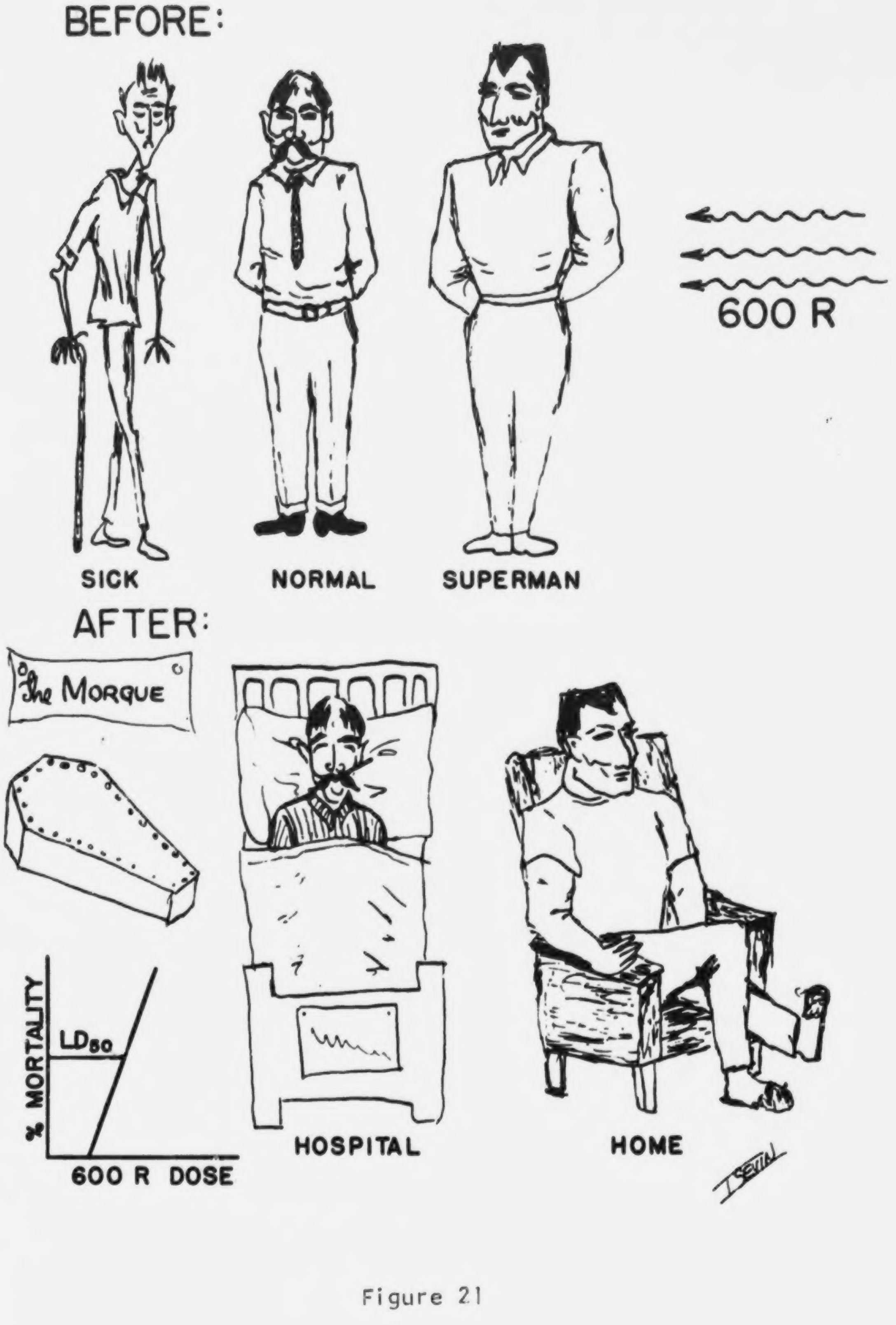

BEFORE:
600 R
SICK
NORMAL
SUPERMAN
AFTER:
The MORQUE
% MORTALITY
LD50
600 R DOSE
HOSPITAL
HOME
I. SEVIN

Figure 21

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RADIATION DOSE-RESPONSE RELATIONSHIPS AND HUMAN DISEASE

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INTRODUCTION

The problem of radiation-induced injury or disease at the human level is of importance to us and to our society because of our increasing use of radioactive material and radiation-producing machines in research, industry, and medicine. The increasing use of these tools presents an increased, yet poorly understood and described, risk to individuals and to the population at large. The problem is of importance to this conference because of the responsibility we have to understand and control this increased risk and because of the ill-defined needs of the various specialists assembled here in meeting this responsibility.

The purpose of this presentation is to provide for us some background information regarding our current knowledge of the types of human disorders that are known to be radiation-induced and the relative quantity of radiation - the radiation dose - that can produce these effects. Consequently, I shall concentrate my remarks on pertinent and currently available information on radiation-induced disease in humans. Hopefully, this discussion will provide some information upon which we can draw during the course of this conference to relate the radiation doses which are experienced in the various medical procedures to possible radiation effects at the human level. This discussion will probably contain no new information for the physicists and radiobiologists in the audience. It should be of more interest to the physicians and it will be particularly helpful for the attorneys.

The nature of this conference excludes a discussion of the genetic effects of radiation, and therefore I shall confine my remarks to somatic effects. The somatic effects of radiation on man, or those effects manifested during the individual's lifetime, are dependent upon a number of physical and biological factors. Generally, when these factors are adequately identified and described, the somatic effects can be related to the radiation absorbed dose or the radiation dose measured in rads. A description of this kind is commonly referred to as a radiation dose-response relationship. Dr. Willhoit will undoubtedly expand and explain more completely the concept of radiation dosimetry for you.

Because observations of radiation effects on humans are few, some reference will be made to animal experimental data; but, by and large, the conclusions drawn are based on human experience. Several recent reviews (1-5) of this experience are available and have been used in the development of this paper.

DOSE RESPONSE RELATIONSHIPS

In order to understand the nature of the dose-response relationships that I will present to you, a brief discussion of the general types of dose-response relationships is in order. There are two basic parameters that characterize any given radiation dose-response relationship. The first is the existence of nonexistence of a threshold dose. By threshold dose we mean a dose of radiation below which the manifest response does not occur. The existence of a threshold dose implies that any radiation dose below this level is safe since the response in question will not be observed. The nonthreshold concept indicates that there is no such thing as a safe radiation dose, since a response presumably would be observed following any radiation dose regardless of how small, if our observation techniques were sensitive enough. The second parameter characterizing the dose-response relationship is its graphical form. If an increase in the dose results in a proportionate increase in the response, the relationship is said to be linear and it will appear graphically as a straight line. Any other relationship is said to be curvilinear.

Figure 1 is an example of a curvilinear, threshold-type radiation dose-response relationship. This graph shows what the current evidence suggests for human lethality within 30 days of a short term radiation exposure to the total body. The ordinate has values ranging from 0 to 100% lethality, and the abcissa contains radiation doses ranging from 0 to 1000 rads. As shown by the hashed lines, presumably 450 rads of total body radiation will be lethal to 50% of the exposed persons. Since the S-shaped curve intersects the abscissa at approximately 200 rads, we would expect to see no lethality in human population irradiated with doses from 0 to 200 rads. Total population lethality would be observed above approximately 800 rads.

An example of a linear, nonthreshold dose-response relationship is shown in Figure 2. This graph shows the relationship between the dose of radiation administered to patients treated for ankylosing spondylitis, a spinal disorder, and the subsequent incidence of leukemia. The regression line has been drawn from the data from the study of Court-Brown and Doll (6). This relationship suggests that any radiation exposure, regardless how small, carries a finite risk of producing leukemia. However, a number of qualifications and assumptions are required for that statement. They are discussed later in this paper.

Radiation dose-response relationships based on human somatic and gentic injury have been the basis for radiation protection standards since the 1920s. Until 1956, these radiation protection standards were based upon the assumption of a threshold-type dose-response relationship (7). After years of debate and thoughtful investigation by radiation scientists, the basis for the establishment of radiation protection standards was changed primarily because of genetic considerations, to accomodate a linear, nonthreshold-type radiation dose-response relationship (8). This change in philosophy was accompanied by a three-fold reduction in the recommended maximum permissible dose. The Federal Radiation Council in 1960, established a series of radiation protection guides which were based on the same

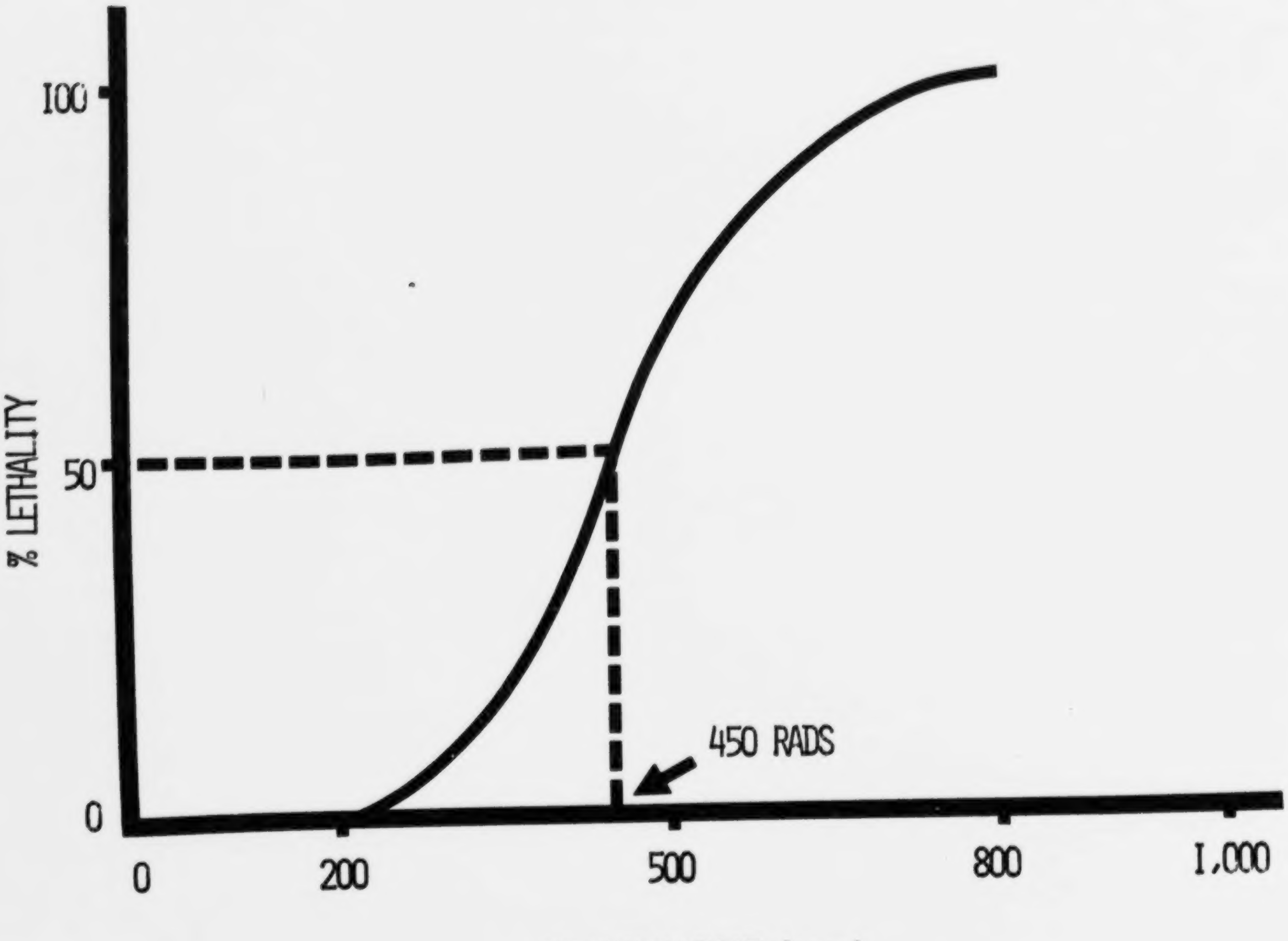

FIGURE I

LETHALITY IN HUMANS WITHIN THIRTY DAYS OF A SHORT TERM EXPOSURE TO X OR Y RAYS.

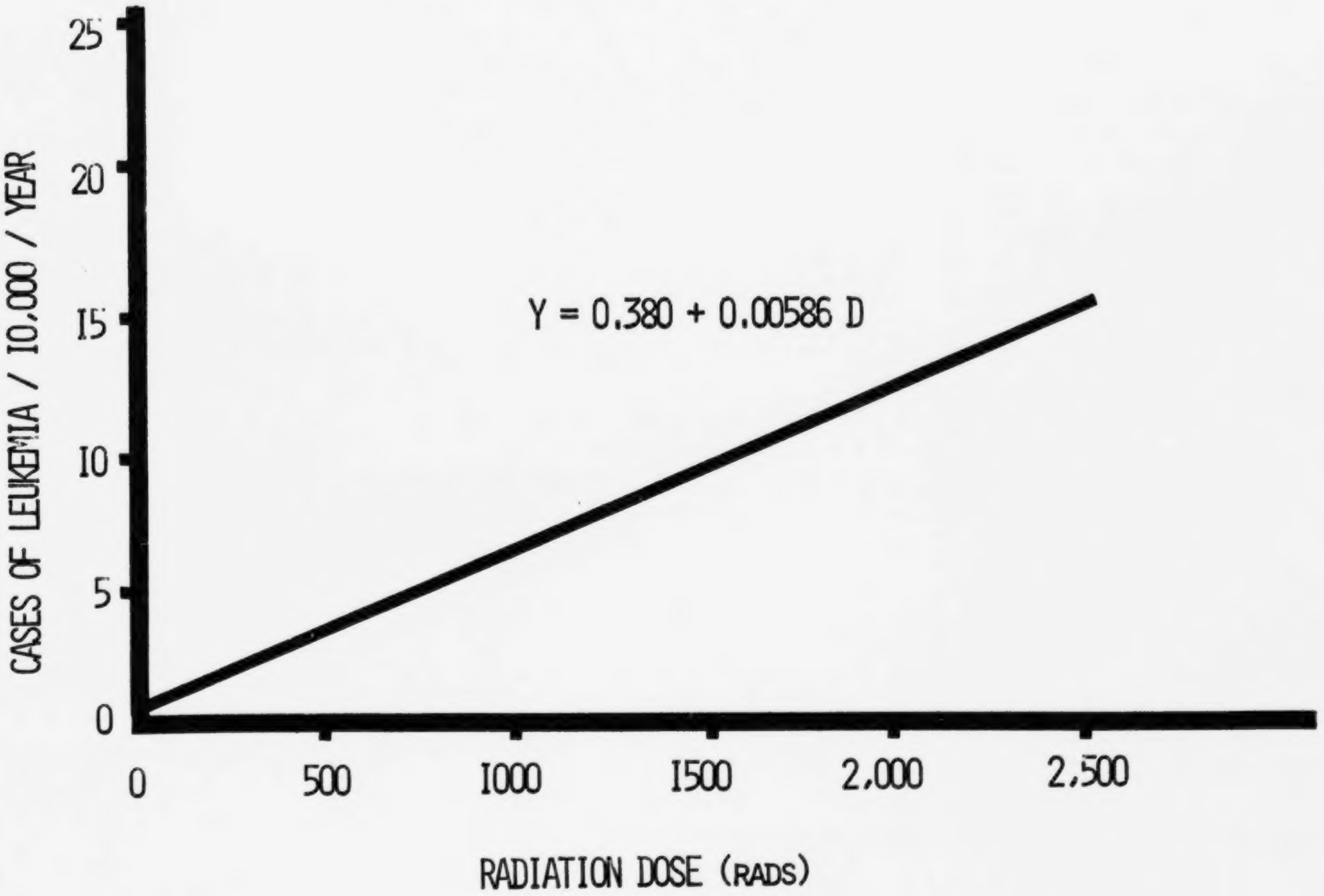

FIGURE 2

THIS LINE REPRESENTS THE BEST LINEAR FIT TO THE DATA OF COURT BROWN AND DOLL. THE DATA ANALYSIS RESULTS IN APPROXIMATELY 0.6 CASES OF LEUKEMIA / MILLION AT RISK / RAD.

linear, nonthreshold dose-response relationship that earlier had been presumed by the National Council on Radiation Protection (9).

The use of a linear, nonthreshold dose-response relationship as the basis for radiation protection standards seems to be justified and is accepted as valid by most radiation scientists. The available experimental evidence relating to the genetic effects of radiation, though not totally consistent, does support a linear, nonthreshold dose-response relationship. The same cannot be said about the somatic effects of radiation at the human level. No generalization regarding somatic effects can be made because the shape of the dose-response relationship is influenced by too many variables - the observed response, the time dependent distribution of the response, and the spatial and temporal distribution of the radiation dose. One great difficulty in analyzing human somatic responses to radiation is the paucity of available data. Further, the data that is available usually relates to high radiation doses and very readily observed and measured responses. Extrapolation from the high dose, measurable response level to the low dose, immeasurable response level cannot be made with confidence. To extrapolate from the measurable region of this relationship to the immeasurable region involves very large and questionable assumptions. For example, Figure 3 shows four possible extrapolations (the hashed lines) of measurable data (the solid line) into the low dose region. Three of these extrapolations assume a nonthreshold type response. Three of the extrapolations are curvilinear and therefore may require additional assumptions regarding the precise shape of the curve in the high dose region. Consequently, one will get a very different estimate of the response following a low radiation dose, depending upon the assumptions that one makes in extrapolating from the measurable region of the dose-response relationship.

Our primary concern during this conference is with radiation doses at the very low end of the dose-response relationship, usually in the immeasurable region of the relationship. It is always difficult, if not impossible, to differentiate between radiation-induced disease following low radiation doses and naturally occurring disease. It is equally as difficult to assign a probability value in these instances.

HUMAN RADIATION RESPONSES

This brief description of radiation dose-response relationships should provide sufficient background information to investigate the pertinent available data from human experiences. We can catagorize human responses to ionizing radiation according to whether they are manifested immediately following exposure or at sometime thereafter. The immediate or early radiation effects are usually easily recognizable and result from high radiation doses. The delayed or late effects can be more difficult to identify and can result from much smaller radiation doses.

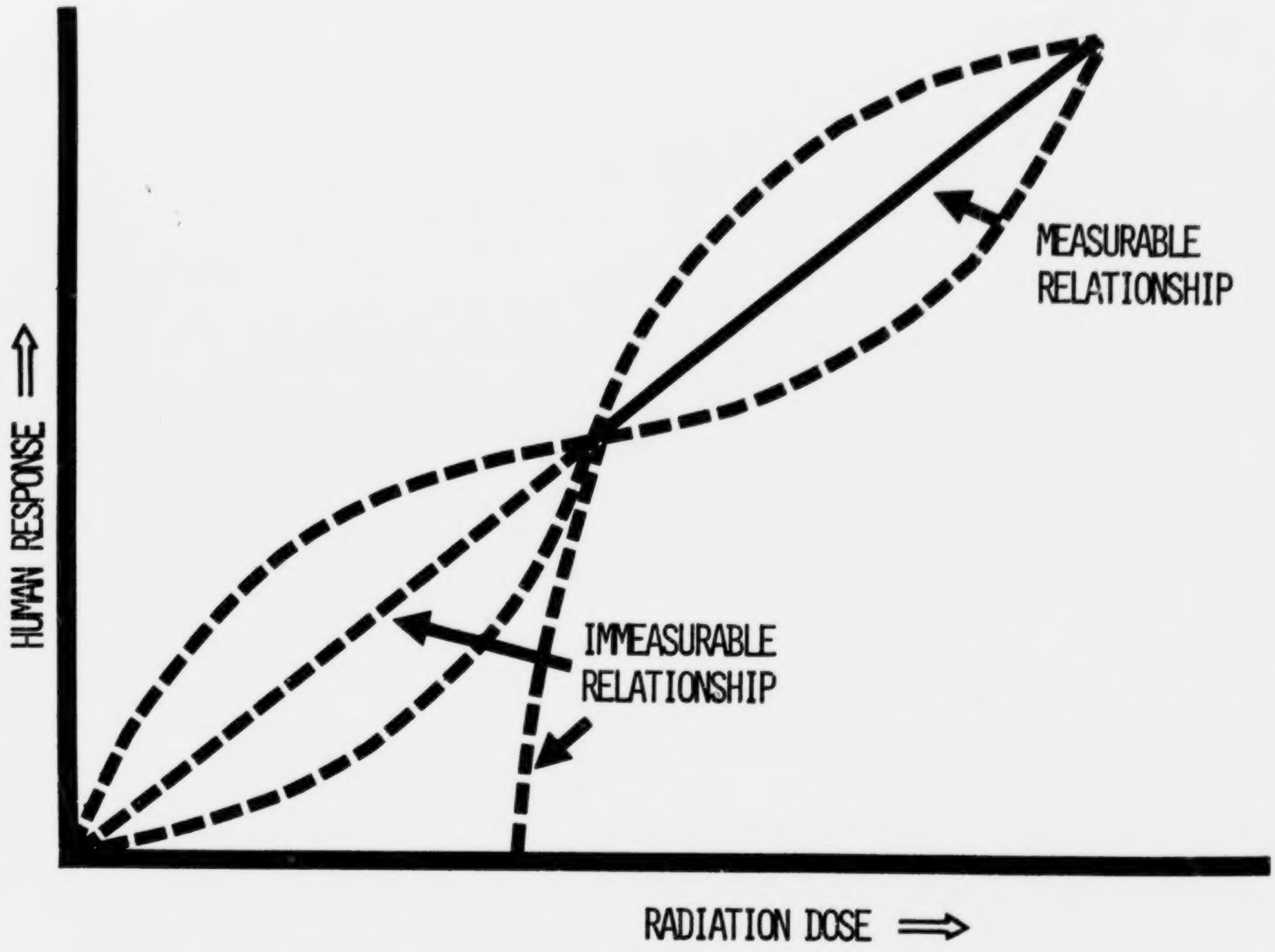
HUMAN RESPONSE ⇒
MEASURABLE RELATIONSHIP
IMMEASURABLE RELATIONSHIP
RADIATION DOSE ⇒

FIGURE 3

THE EXTRAPOLATION FROM A MEASURABLE RELATIONSHIP TO THE LOW-DOSE, IMMEASURABLE REGION REQUIRES ASSUMPTIONS REGARDING THE PRESUMED SHAPE OF THE CURVE.

A. Early Responses to Radiation Exposure.

It is not always possible or practicable to distinguish between early and late effects of radiation on man; however, for the purpose of our discussion, we may consider the early effects to occur from immediately following radiation exposure, to within a week or so of exposure, while the delayed effects may occur months or years following exposure.

1. Lethality

There are primarily four early effects of radiation that deserve our attention. First is the lethal response to radiation. Evidence for the construction of a dose-response relationship based upon human lethality comes primarily from animal experimentation. Some additional data, however, is available from the irradiated populations of Hiroshima and Nagasaki, and from the few fatal radiation accident cases. Collectively, these data show three distinct modes of radiation-induced death. Following exposure to several thousand rads of total body dose, the individual will undergo severe neurological disorders and die within hours. This radiation response is commonly referred to as the central nervous system syndrome. When the radiation dose is within the range of approximately 800 - 2500 rads, gastrointestinal disorders occur within hours, subside for a few days, reoccur and result ultimately in death within 7 - 10 days. This mode of death is known as the gastrointestinal syndrome. With radiation doses between 200 - 800 rads, gastrointestinal disorders might appear within a few hours and then subside. In a week to ten days a progressive hematologic depression would be observed which might lead ultimately to hematologic failure and death. These relationships between radiation dose and lethality can be represented in two ways. Figure 4 is a plot of the mean survival time of an individual as a function of the radiation dose. The three regions of this curvilinear relationship have been identified with the three acute radiation syndromes. The low dose steep portion of the curve relates to the hematological syndrome. The plateau relates to the gastrointestinal syndrome and the high dose, steep portion corresponds to the central nervous system death. Note that this relationship is expressed on a log-log plot and the units along the ordinate are hours. Another expression of the lethal dose-response relationship has been shown in Figure 1. It graphically presents the relationship between radiation dose and the percentage of the population which would die following a radiation exposure. Among other things this relationship demonstrates the narrow range of radiation doses - 200 to 800 rads - that would result in a questionable prognosis. Outside of these ranges, the outcome is nearly certain.

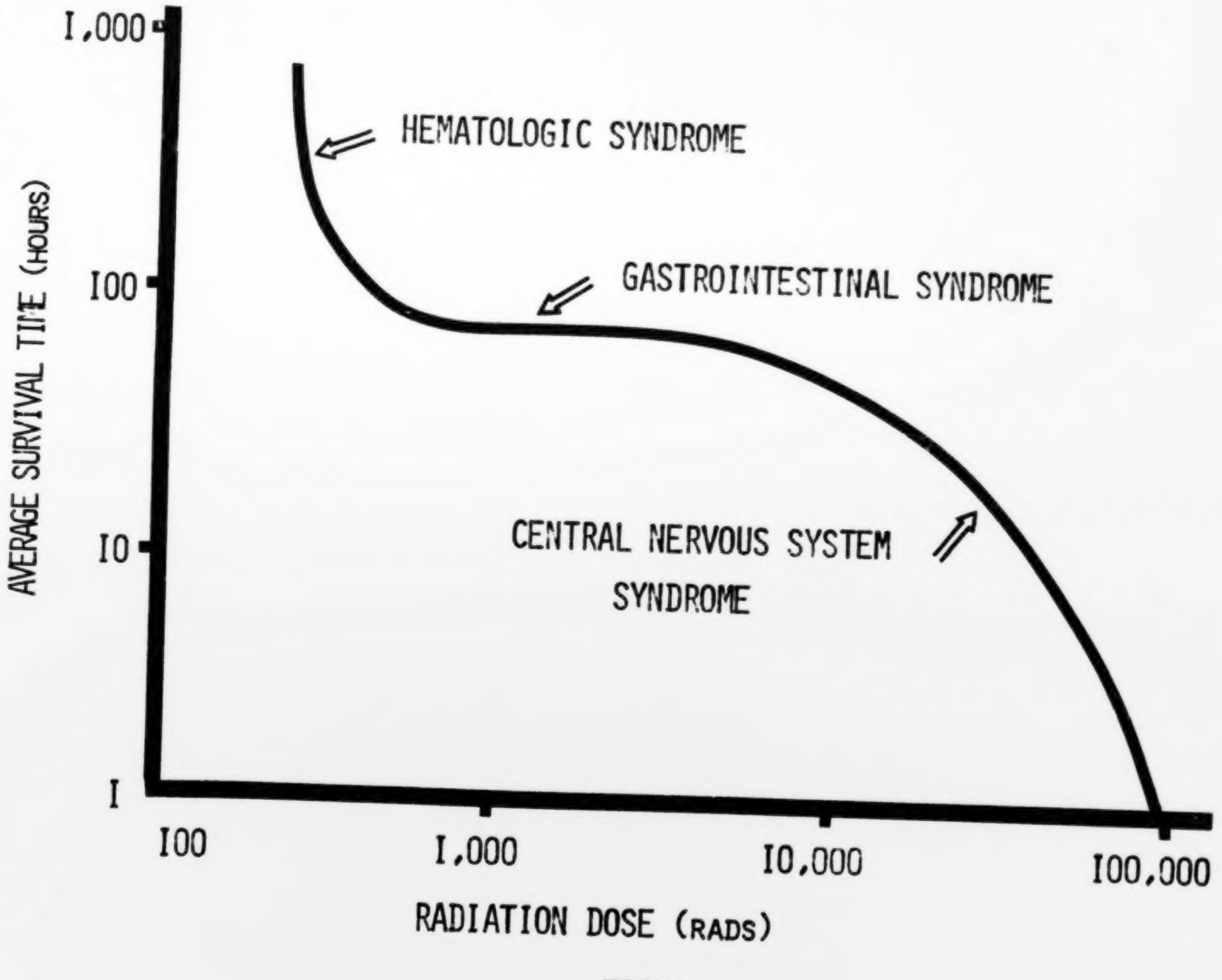

FIGURE 4

THE RELATIONSHIP BETWEEN RADIATION DOSE AND THE AVERAGE HUMAN SURVIVAL TIME FOLLOWING A SHORT TERM EXPOSURE.

2. Hematological depression.

The circulating blood of man is one of the most sensitive tissues to radiation exposure. Following relatively low doses of radiation, 25 rads and above, changes in the number of cells of each of the cell types in the circulating blood are observed and collectively result in hemtological depression. This depression is dose-related in a complex way, and in the absence of radiation measuring instruments, may be used with some satisfaction as a prognostic indicator of radiation damage. Indeed, until the middle 1950's, periodic blood examination was recommended for occupationally exposed persons. This practice was discontinued, however, when it became apparent that no measurable hematologic change resulted from occupational levels of radiation exposure. The common result of radiation exposure on the circulating blood can be demonstrated best by Figure 5. This graph shows the post-irradiation changes to be expected in the circulating blood following exposure to approximately 200 rads of x-radiation. The important parameter on this graph is the curve related to the leukocyte, or white cell, concentration. Following exposure, there is a rapid transient increase in the leukocyte count followed by severe depression, which reaches a minimum value in approximately 30 days. Recovery to the normal leukocyte level is usually achieved in 120 days depending upon the severity of the depression. The magnitude of the initial increase in the leukocyte concentration and the later depression are both dose dependent. Wald and Thoma (10) have analyzed the hematologic data from 32 human radiation accident cases and have constructed a dose-response relationship based on a compounded score of hematologic values at various times post irradiation. This hematologic score might be useful in predicting the course of clinical signs and symptoms and in prescribing a course of supportive therapy.

3. Skin changes.

A third example of the early effects of radiation is represented by skin disorders. Skin erythema and even moist desquamation were common sequelae to radiation therapy in the early days. With the increasing use of high energy radiation and its associated skin sparing properties, these sequelae do not normally result from current radiation therapy procedures. The dose-response curves shown in Figure 6 may be misleading in that they appear as straight lines on probability paper. On a linear plot, these would be threshold curvilinear type relationships. The relationships shown in Figure 6 are from the work of Duffy et al (11) and represent skin responses to single doses of 200 kVp x-rays.

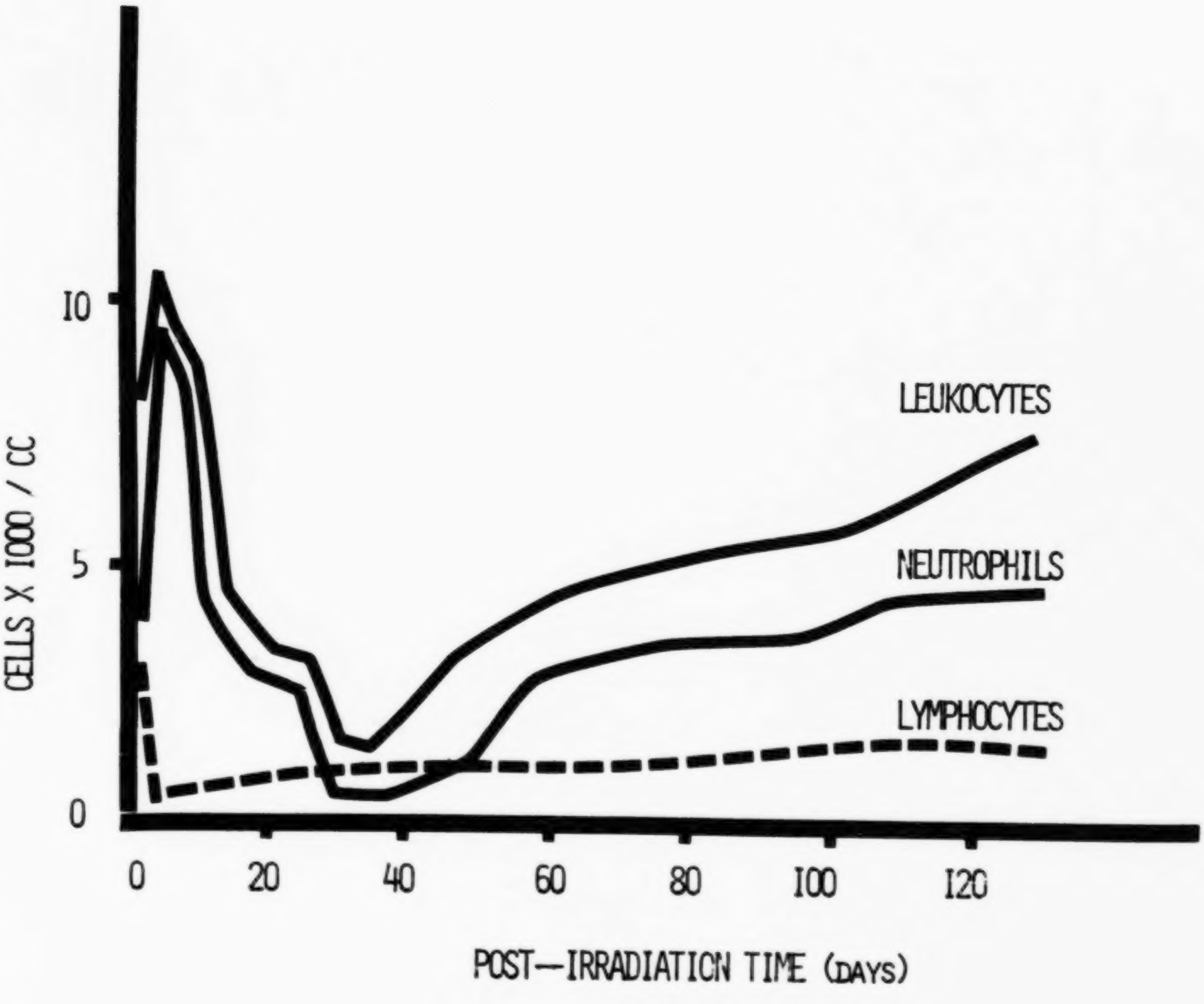

FIGURE 5

CHARACTERISTIC RESPONSE OF LEUKOCYTES, NEUTROPHILS AND LYMPHOCYTES FOLLOWING APPROXIMATELY 200 RADS OF X OR γ RADIATION.

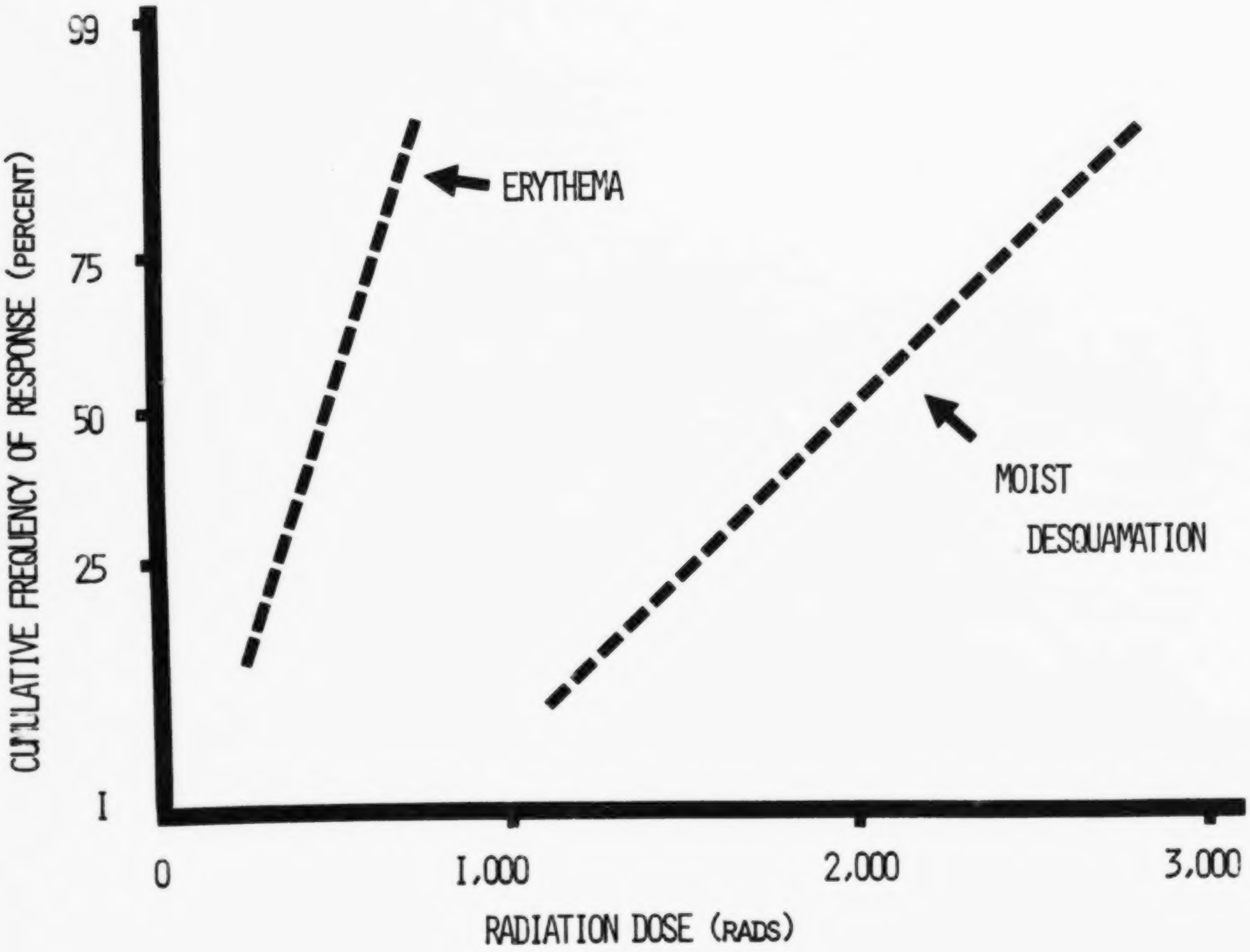

FIGURE 6

THE RESPONSE OF HUMAN SKIN TO SHORT TERM DOSES OF 200 kVp X-RAYS (REPLOTTED FROM DUFFY).

4. Cytogenetic damage.

A final important early manifestation of radiation exposure is the production of chromosome aberrations in the peripheral blood and bone marrow of man. If one cultures the leukocytes from the circulating blood or bone marrow cells of an irradiated individual, the chromosomes of those cells can be made to appear distinct and individually identifiable as shown in Figure 7. Then the number of chromosome aberrations per cell can be determined and used to compute an aberration frequency for several dose levels. This will result in a dose-response relationship of the form seen in Figure 8. These data are from some of our work (12) involving cultured human cancer cells irradiated *in vitro*. This quadratic dose-response relationship has been shown to be balid for a numb er of cell lines following both *in vivo* and *in vitro* irradiation. Chromosome aberrations are easily observed following a course of external beam radiotherapy (13) and have been reported following radioisotope procedures (14) and diagnostic x-ray exams (15). However, the relationship between cytogenetic damage and latent physiological change is unknown.

Cytogenetic techniques have been available only a few years and, therefore, their ultimate utilization has not been realized. Using these techniques, measurable chromosome damage has been recorded following radiation doses as low as 5 rads and this level of sensitivity promises to be increased. With the coming of computer technology coupled to cytogenetic analysis (16), this procedure offers promise of being an extremely sensitive and reliable biological radiation dosimeter.

5. Summary.

The early responses to radiation exposure occur following high radiation doses and are usually easily measured. Human lethality results from doses above about 250 rads. Skin erythema can be produced with radiation doses greater than approximately 400 rads. Hematologic depression may be measured following as little as 25 rads, and cytogenetic damage can be seen following approximately 5 rads.

B. Late or Delayed Responses.

The primary delayed effects of radiation can be classified into three broad categories - local tissue damage, life span shortening, and induction of malignancy. Other conditions associated with the normal aging process may be enhanced in time and intensity by prior radiation exposure, but there is insufficient evidence to confidently relate radiation exposure to those conditions.

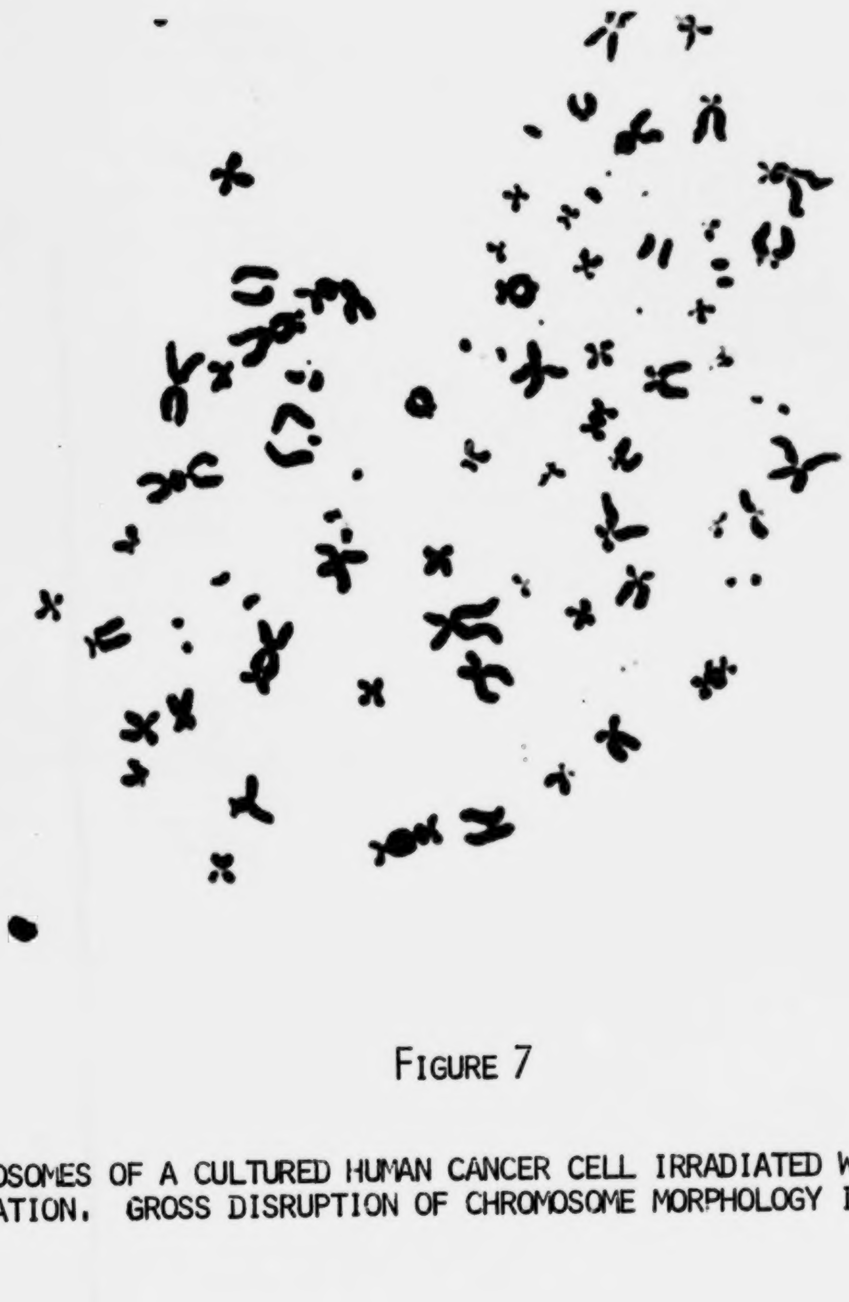

FIGURE 7

THE CHROMOSOMES OF A CULTURED HUMAN CANCER CELL IRRADIATED WITH 1032 RADS OF X-RADIATION. GROSS DISRUPTION OF CHROMOSOME MORPHOLOGY IS SHOWN.

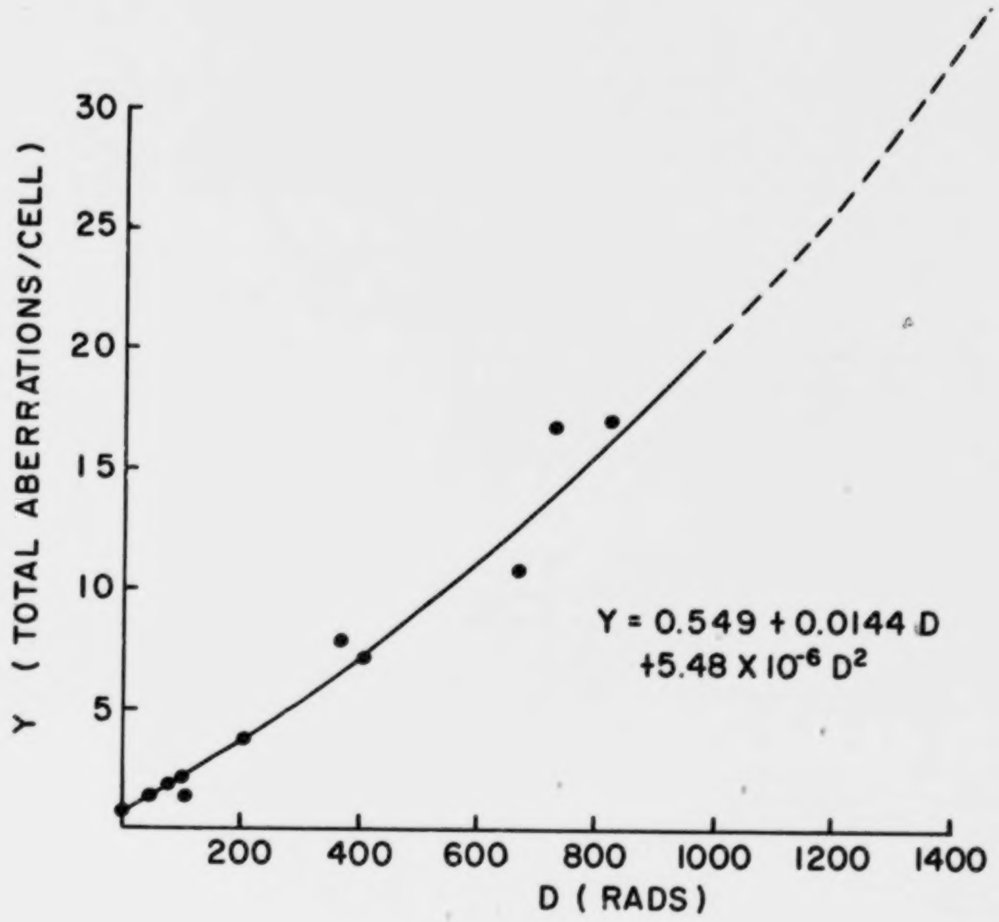

FIGURE 8

THIS RADIATION DOSE-RESPONSE RELATIONSHIP IS BASED ON CHROMOSOME ABERRATIONS IN HUMAN CANCER CELLS IRRADIATED IN VITRO. THE RELATIONSHIP IS QUADRATIC IN FORM.

1. Local tissue damage.

A prime example of radiation incuded local tissue damage is cataract formation. Several hundred instances of cataract in man have been attributed to prior radiation exposure. These lens opacities have been detected after doses as low as 200 rads, although for the production of clinically significant cataracts a dose greater than approximately 600 rads is necessary and a latent period of two to eight years is required. A simple dose-response relationship is not possible with this type of injury because of limited information and because cataract formation apparently is very dependent upon a number of physical and biological factors. One of the largest population study groups available are the survivors of Hiroshima and Nagasaki. Examination of approximately 8,000 of these exposed survivors eleven years post irradiation showed only 10 cases of severe cataract formation.

Radiation can cause sterility and this is another example of local tissue damage. A dose to the gonads of greater than approximately 500 rads will produce permanent sterility in most people. With a gonadal dose of approximately 250 rads, temporary sterility may be induced for a period of several years. With gonadal radiation doses of less than 200 rads, temporary sterility or subfertility may be induced.

Delayed skin effects may follow radiation doses of several hundred rads and they increase in frequency and severity with increasing radiation dose. These effects are dependent upon a number of factors other than dose, especially the size of the exposed area. The changes that appear are many and when they are observed collectively they are referred to as chronic radiodermatitis.

2. Lifespan shortening.

A great deal of convincing evidence has been generated through animal experimentation to show that sublethal radiation reduces lifespan. Additionally, this life span shortening apparently is closely related to the radiation dose and its temporal distribution. Although extrapolation from animal to man is hazardous, the animal data has resulted in a linear, threshold type relationship between radiation dose and lifespan shortening. One form of this relationship is shown in Figure 9 where the curve relating decreased survival time as a function of the lethal dose of radiation is a generalized representation. Epidemiological studies of radiologists and other physician specialists (17) have demonstrated that occupational radiation exposure in the past did result in decreased longevity for these physicians - approximately five years for radiologists.

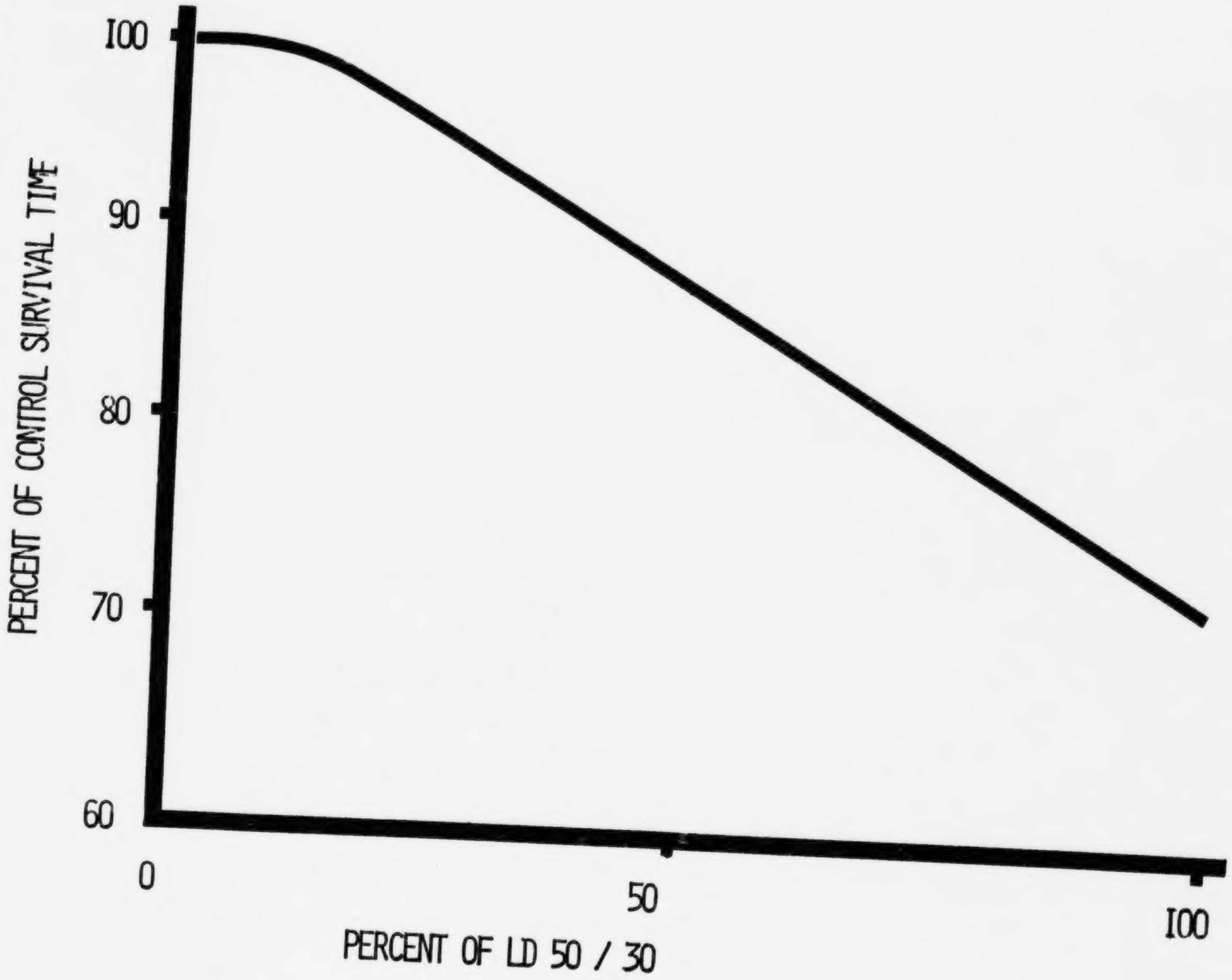

FIGURE 9

THIS CURVE REPRESENTS THE APPROXIMATE RELATIONSHIP BETWEEN LIFESPAN SHORTENING AND SHORT TERM RADIATION DOSE FOR RODENTS.

This decreased longevity has disappeared in recent years (18), presumably due to better radiation safety practices. Estimates based on a linear extrapolation of animal and human data would suggest that a loss of 10-20 days of life per rad of exposure might be expected.

3. Leukemogenesis.

It is known that radiation can cause leukemia and other malignancies. A great deal of information on human radiation-induced malignancy has been developed from primarily four population groups - the Hiroshima and Nagasaki survivors, radiologists, radiation therapy patients, and children irradiated in utero. The effects of high dose irradiation on these populations has resulted in a well established dose-response relationships. At low doses, however, the results are inconsistent and equivocable. Our discussion here will center on radiation-induced leukemia, although similar findings, based on less data, have been reported for other malignancies.

Studies of the atomic bomb survivors have shown that, out of a population at risk of something over 100,000 persons, about 200 cases of leukemia have been detected. This represents a greater than ten fold increase over the ambient level of leukemia. Further investigation of these data show an apparent linear dose-response relationship at the high dose level. This is shown in Figure 10. The slope of this dose-response curve indicates that approximately 1 to 2 cases of leukemia per year per rad per million of exposed persons would be expected. Extrapolation of this relationship below approximately 100 rads is mere speculation. There findings have been supported and extended in a recent paper by Bizzorzero, Johnson and Ciocco (19).

Studies of excess mortality due to leukemia among early radiologists have generally resulted in an approximate threefold increase in leukemia incidence above that of the general population. This increase incidence of leukemia in radiologists could not be directly related to dose because of the long term, fractionated exposure and the lack of precise dosimetric information. However, estimates have placed the long term dose to be at least 100 rads. Current mortality records show no difference in leukemia incidence between radiologists and the general public.

Patients with ankylosing spondylitis, a disorder of the spine, received large field radiation treatments for this malady. They represent another population study group who developed leukemia at an increased rate over that for the general population. The radiation treatments were not total body, but were confined to

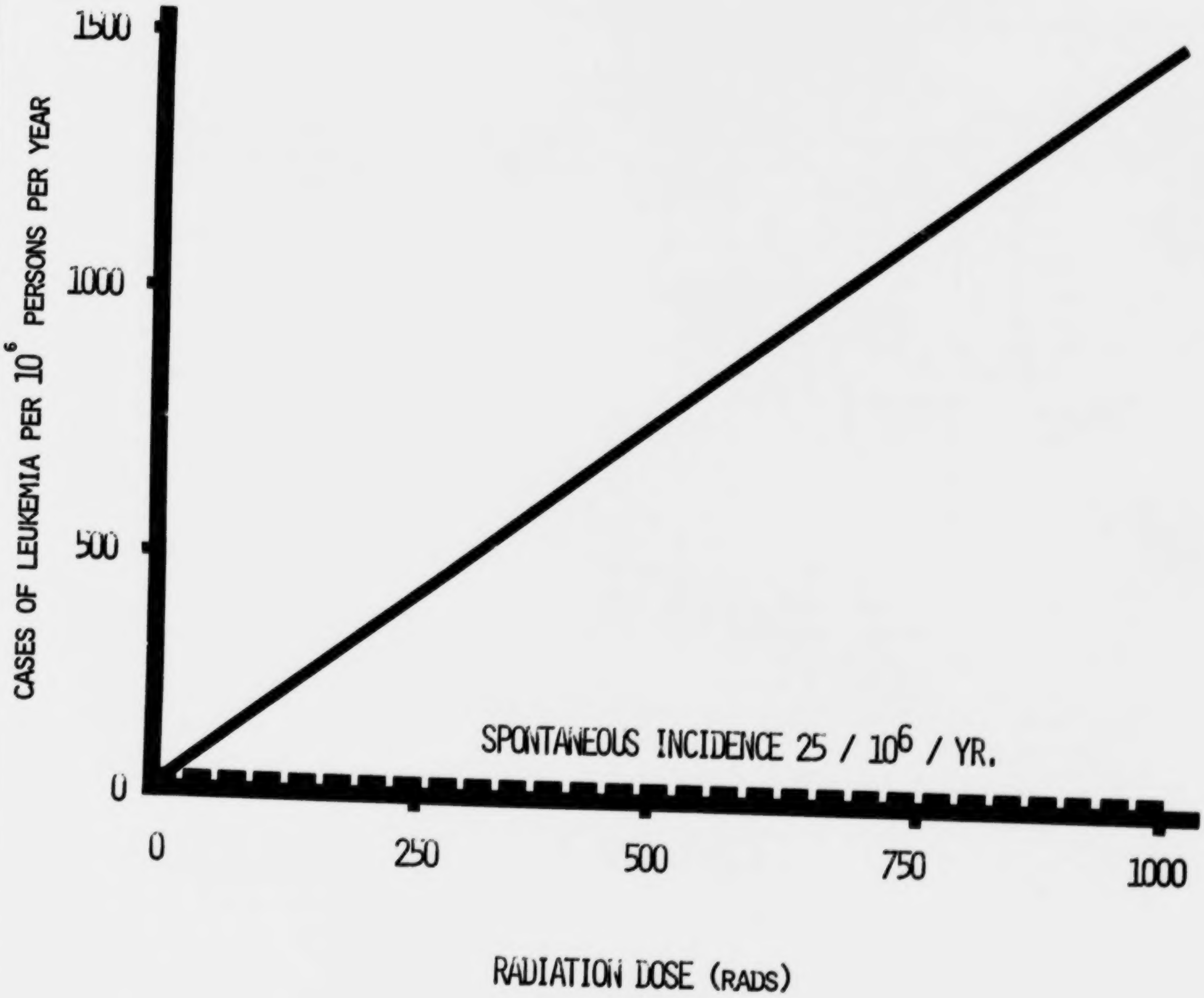

FIGURE 10

THE REGRESSION LINE REPRESENTS THE AVERAGE INCIDENCE OF LEUKEMIA IN THE ATOMIC BOMB SURVIVORS OF HIROSHIMA AND NAGASAKI AS A FUNCTION OF RADIATION DOSE.

a major portion of the active bone marrow. Figure 2 is drawn from the data of Court-Brown and Doll (6) which contained fewer than 40 cases in a study population of approximately 13,000 patients. Therefore, although the radiation dosimetry record was complete, extrapolation of this data below about 250 rads is conjectural. This regression line has a slope of 0.5 in the radiation dose range of approximately 250 rads to 1500 rads. Therefore, in this dose range, the average incidence of leukemia was 0.5 cases per rad per million patients. These values are of the same order as those obtained from the analysis of the atomic bomb survivors.

The final, and currently most publicized, population studied for radiation-induced leukemia is composed of children irradiated *in utero* or in early childhood. Most studies of this population point to an increase incidence of leukemia in these children; however, the number of leukemia cases is so small that statistically significant differences from the control groups cannot be demonstrated. These studies have produced inconsistent yet suggestive results. Collectively, the results suggest that a relative risk factor of 1.5 is associated with diagnostic x-irradiation *in utero*. Recent data (20) from a study involving 3024 children, 1008 of whom received x-ray exposure *in utero*, shows no significant increase in the number of leukemia cases in the irradiated group over the control group. However,the numbers involved in this study may have been too low to result in a measurable response. Analysis of the data on children irradiated postnatally for thymic enlargement is similarly equivocable and therefore a dose-response relationship based on these data is not possible. Since 1964 U.N. report (2) which surveyed many studies and arrived at this conclusion, an extensive study by Graham *et al* (21) and a review by Stewart and Hewitt (22) have produced further inconclusive yet suggestive results.

Additional analysis of many of the above studies has recently been presented by Sternglass (23). He points out that, although the frequency of leukemia was low in the childhood studies, the temporal distribution and age distribution of leukemia was similar for all of the population groups. His analysis suggests that leukemia is produced by low radiation doses, even at low dose rates approaching natural background levels.

4. Carcinogenesis.

What has been said about radiation-induced leukemia can be said for other types of radiation-induced malignancy. Less confidence is held for radiation carcinogenesis because there are fewer studies and fewer cases than those available for radiation leukemogenesis. The data that is available suggest that high doses of radiation cause cancer, but dose-response relationships cannot be developed at doses less than several hundred rads. A number of malignancies - thyroid cancer, skin tumors, bone tumors, and lung cancer - have been related grossly to radiation exposure. Thyroid cancer comprises the largest of these study groups (24, 25). The incidence of thyroid cancer appears to be dose-related over the dose range of approximately 300-600 rads and apparently has resulted collectively in an average increased incidence of one case per rad per million persons exposed. This level, again, is in the same range as that described for radiation induced leukemia.

5. Summary

The late effects of radiation that are easily measured result from high radiation doses. Late local tissue damage requires hundreds of rads. Lifespan shortening presumably is measured in days of lost life per rad of exposure. Leukemia and cancer are apparently linearly related to radiation dose and occur at the rate of about one case per rad per million at risk.

SUMMARY

In summary, then, we can say that radiation in large doses - hundreds of rads - does produce serious early and late biological effects in man. In this high dose region the observed effect is usually related to the total radiation dose and can be described by a dose-response relationship. Extrapolation of these relationships from the high dose region to the low dose region can be done only with great hazard and hesitation. It should be emphasized additionally that the presumed radiation effects following low doses of radiation are based on either extrapolation from the high dose effects or on the tenuous statistical analysis of very few positive cases available from very large numbers of persons at risk. These facts should be kept in mind because I am sure that later in this conference we will discover that the doses of radiation that we are concerned with in most medical procedures are several orders of magnitude lower than that we have been talking about here. We have considered radiation doses in this paper in the hundreds of rads. I believe we will hear later that the normal range of radiation doses in diagnostic medical procedures is in the millirad, or thousandths of rads, range.

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RADIATION QUANTITIES AND UNITS AND THE SIGNIFICANCE OF RECORDED MEASUREMENTS

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Introduction

The two previous papers have considered methods of measurement of certain radiation quantities and the relationship between dose and various biological responses. The dose-response curve is a simplified descriptive expression of the relationship of the two variables, dose and response. Inherent in the description of this relationship is the assumption that the dose has a true causal relationship to the observed biological response. There are several radiation quantities that are frequently referred to as "dose" which do not fulfill this condition. In most drug prescriptions the dose of the drug is specified in terms of the number of capsules, teaspoons, drops, etc.; however, the toxicologist prefers to specify dose as the concentration of the drug in the blood or some other organ. Likewise with radiation "prescriptions" we have several methods of specifying dose which include such units as roentgens, rads, and rems. These are units of different kinds of dose, but more importantly they are units of different concepts of dose. To distinguish these different concepts consider the illustration in Figure 1. Three locations, A, B, and C, are shown in an X-ray beam with and without a patient. Radiation measurements made without the patient give an indication of a quantity referred to as exposure. Exposure is defined in terms of the ionization produced "in air" by X- and gamma radiation (1). The special unit of exposure is the roentgen (R) and can be used only for the specification of the quantity of ionization produced in air in multiples of esu/0.001293 g of air.

The radiation quantity considered most relevant from a biological stand-point is the energy absorbed per unit mass of tissue, or absorbed dose (1). The concept of absorbed dose is best illustrated by considering locations A and C on the patient in Figure 1. The total energy reaching the X-ray film at C will be less than the total passing the patient's skin at A due to absorption in the patient. Thus, the energy absorbed in the patient will be equal to the difference in the energy passing through the areas defined by the X-ray beam at A and C. If we consider any small volume within the patient (e.g., location B), the energy absorbed is equal to the difference in the quantity of radiation entering and leaving the volume. The special unit of absorbed dose is the rad which is equal to an energy absorption of 100 ergs per gram.

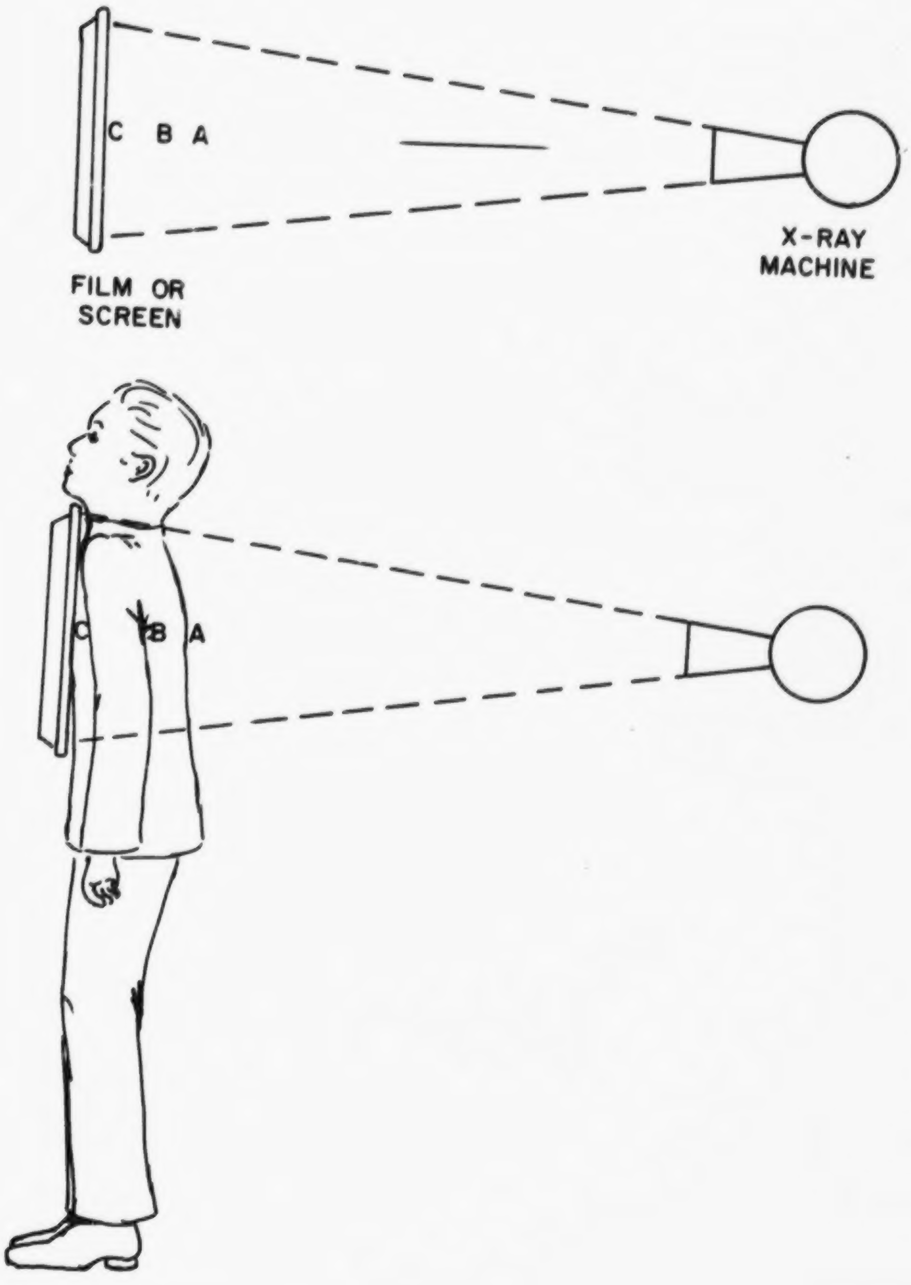
C B A
FILM OR SCREEN
X-RAY MACHINE
C B A

Figure 1. Exposure (above) vs. dose (below)

Another unit somewhat related to the rad is the integral absorbed dose, which is equal to the total energy absorbed in a specified region. Thus, in Figure 1 the integral dose is equal to the difference in the total energy passing through the surface areas defined by the X-ray beam at locations A and C. The unit of integral dose is the gram-rad. One gram-rad is simply an energy absorption of 100 ergs ($1g\text{-rad} = 1g \times 100 \frac{ergs}{g}$).

Roentgens to Rads

Dose specified in roentgens is often used interchangeably with dose specified in rads and thus implies that some degree of equivalence exists. The fact that roentgen and rad refer to different concepts should indicate that there is more to such a conversion than simple arithmetic. Therefore it is necessary to convert exposure to absorbed dose, i.e., ionization (in air) to energy absorbed in tissue. This requires a knowledge of the average energy expended per ion pair produced and also the relative absorption characteristics of tissue compared with air for the radiation in question. In addition, due to the importance of scattering it is necessary to define the geometry of the absorbing material and the point within the geometry at which the absorbed dose is specified. To simplify the situation, the conversion of roentgens to rads is usually qualified by stating that the calculation is that of the absorbed dose in a "small" (small enough that scattered radiation has a negligible chance of interacting, but large enough to insure electron equilibrium) mass of tissue placed at the point of interest in the exposure field. Under these conditions, for X- and gamma radiation up to a few MeV, it is found that an exposure of 1 R results in an energy absorption of approximately 95 ergs per gram of tissue, or approximately 1 rad. However, the absorbed dose in specimens large enough to allow scattered radiation to interact, cannot be calculated in such a straight forward manner. If the "point of interest" is within the body (eg, location B in Figure 1) the absorbed dose will not be equal to the exposure, but will be modified due to scattered X-rays and attenuation of the X-ray beam by the tissue between locations A and B.

Figure 2 indicates the variation in absorbed dose as a function of depth in tissue. The curve marked "primary" indicates the decrease in absorbed dose due to attenuation of the radiation by the tissue. The initial value (depth of 0 cm) of absorbed dose in the "primary" curve is the value calculated for the "small" mass of tissue. The curve labeled "scatter" indicates the absorbed dose due to X-rays that have interacted elsewhere in the tissue, are scattered, and then interact again. The total absorbed dose is the sum of the absorbed dose due to primary plus scattered X-rays. The ratio of the total absorbed dose at the skin surface to the absorbed

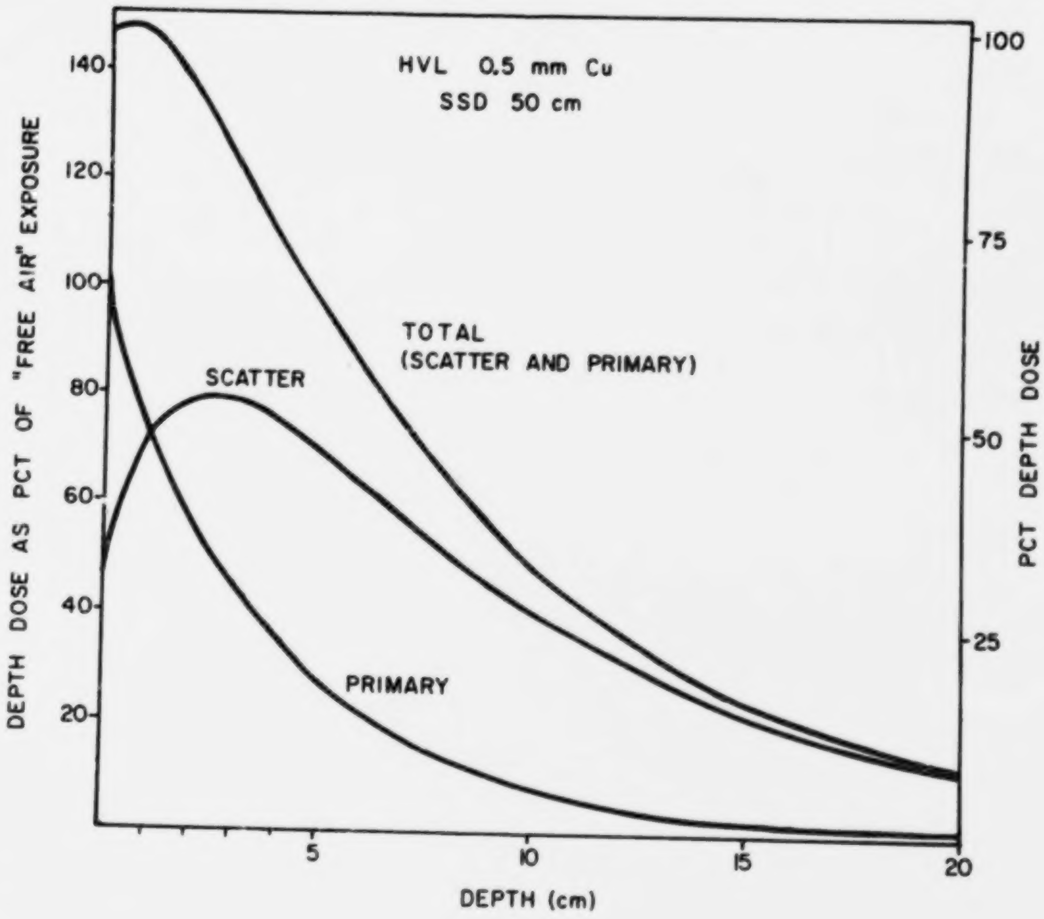

Figure 2. Absorbed dose as a function of depth in tissue

dose due to primary radiation is referred to as the backscatter factor and is equal to approximately 1.5 in Figure 2, or in other words, the scattered radiation accounts for 50 per cent of the absorbed dose at the skin surface. If a film badge or other suitable monitoring device were placed on the patient at location A, it would give an indication of the surface absorbed dose due to the primary plus scattered X-rays.

Since certain late-effects of irradiation, such as leukemia, are considered to be due to irradiation of the bone marrow, it is of interest to determine the absorbed dose to the bone marrow for the distribution depicted in Figure 2. At a depth of 5 cm, the effective depth of the bone marrow, the absorbed dose is 97 per cent of the exposure value, but only 66 per cent of the surface absorbed dose.

The ideal quantity for specification of dose from the standpoint of radiation protection would be one which would produce the same biological effect or risk of biological effect independent of the physical nature of the radiation, the manner in which it is delivered, or its distribution within the body. Because the theoretical basis of such a unit has not been established, the method of approach for purposes of radiation protection has been to measure physical quantities which are thought to be important from the response standpoint and apply empirical correction factors. Dose equivalent is such a quantity which is defined for the purpose of describing on a common scale the biological efficiency of a non-standard radiation (or standard radiation delivered under non-standard conditions) compared to a standard radiation.

The dose equivalent, (DE), is defined as the product of absorbed dose, D, quality factor, (QF), dose distribution factor, (DF), and other necessary modifying factors.

$$(DE) = D(QF)(DF)\ldots.$$

The special unit of dose equivalent is the rem which is numerically equal to the absorbed dose in rads multiplied by the appropriate modifying factors. It should be noted that specification of dose equivalent alone is not sufficient since the critical organ must also be specified (Table I). Thus far, values of QF have been defined only for heavy charged particles, but not for various X-ray qualities. Likewise, values of DF have not as yet been proposed for non-uniform external irradiation, but only for internally deposited radioactive materials.

Recorded Measurements

Much of the controversy regarding the significance of personnel monitoring measurements and records has been due to a misunderstanding of what is being measured and

TABLE I

Permissible Doses of Radiation to Restricted Areas

	Portion of Body	Rems per calendar quarter
1.	Whole body; head and trunk; active blood-forming organ; lens of eyes; or gonads	1 1/4
2.	Hands and forearms; feet and ankles	18 3/4
3.	Skin of whole body	7 1/2

recorded and the philosophy or intent of the measurement. This may largely be due to the looseness in terminology in describing radiation quantities for regulatory requirements. To illustrate the point consider the following excerpts from 10 CFR 20 (2), paragraph 20.4, Units of Radiation Dose:

> "Dose as used in this part is the quantity of radiation absorbed, per unit of mass, by the body or by any portion of the body." ..."The rad as used in this part is a measure of the dose of any ionizing radiation to body tissue in terms of the energy absorbed per unit mass of the tissue."
>
> "The rem as used in this part is a measure of the dose of any ionizing radiation to body tissue in terms of its estimated biological effect relative to a dose of one roentgen of x-rays. ...for the purpose of the regulations in this part, any of the following is considered to be equivalent to a dose of one rem: 1) a dose of one R due to X- or gamma radiation; 2) a dose of one rad due to X-, gamma, or beta radiation; ..."
>
> "For determining exposures of X- or gamma rays up to 3 MeV, the dose limit specified in 20.101 to 20.104, inclusive, may be assumed to be equivalent to the 'air dose'. For the purpose of this part 'air dose' means that the dose is measured by a properly calibrated appropriate instrument in air or near the body surface in the region of the highest dosage rate."

After comparison of these definitions with those of the ICRU it is not surprising that much confusion exists regarding the significance of recorded "doses". Aside from the use of "dose" to refer to exposure, absorbed dose, and dose equivalent, the important difference to note between 10 CFR 20 "dose" and ICRU absorbed dose or dose equivalent (which is defined in terms of absorbed dose) is the treatment of dose distribution. Obviously, if the recorded measurement is a single number, indicating only the maximum absorbed dose, without reference to area of body exposed or distribution within the body, it would appear to be of little value in interpreting later biological responses.

If the purpose of the radiation exposure record is to provide sufficient dosimetric information for evaluation of the biologically significant dose then a single number is inadequate in view of the current state of the art.

What Constitutes an Adequate Radiation Exposure Record?

If the purpose of the radiation exposure record is to provide a check on the adequacy of the radiation protection program then the single number method required by 10 CRF 20 is adequate since it is on the conservative side and represents a reading made in the region of the highest absorbed dose.

Even if the dose distribution is known in detail, there is no simple way to reduce the dose distribution to a single number. One method that is often used to specify a non-uniform distribution is the quantity integral absorbed dose which was discussed briefly above. This involves a summation of the product of absorbed dose times the mass of tissue throughout the irradiated region. This presumes that the sensitive tissue is uniformly distributed and that there is a linear dose-response relationship. It has been shown that integral absorbed dose is not the quantity of interest when describing the lethal effects of radiation in animals (4). Recent work by Bond and Robinson(5) indicates that if the integral absorbed dose concept is modified to take into account the distribution of bone marrow and the presumed exponential dose-response relationship of bone marrow stem cells, then such an expression can be useful to calculate the dose equivalent of a non-uniform distribution of absorbed dose. Using this model it should be possible to calculate the dose equivalent for other biological responses if the distribution of the critical organ and the nature of the dose-response relationship for the cellular subunits is known. Therefore, until more is known about basic radiobiological mechanisms complete specification of the physical factors or irradiation should be included in any radiation exposure records intended to provide information relative to the effects low level radiation exposure. The principal factors of irradiation to be considered include (5):

a. target volume

b. type and energy of the radiation

c. method of irradiation

d. pattern of absorbed dose

e. time distribution

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DISCUSSION

DR. COLLINS: In the first three papers we have presented the tools with which to attack the problem. The subject of the conference is contained in the word "litigation." We have in mind a person or group of persons and a problem. The fundamental tools with which this must be approached are the measurement of the radiation agent, the measuring instrument, the unit of measurement and the possible and probable biological effects.

These tools are complicated. Even for those who are the initiates of the field, the data presented are complicated; it is not necessary or valid to present the subject as being simple. Nevertheless, I trust that none in the audience is so cowed by unfamiliar terms or by scientific data that they hesitate to raise a question about the use of this information.

Let me call attention to the possibilities that may occur when answers are offered by expert witnesses and received by the court. A correct answer may be presented and believed. The answer may be correct but not believed. It may be correct and misrepresented or misinterpreted. It may be correct, but irrelevant and not significant. It may be in error and rejected. It might be in error but now accepted.

These are the ground rules within which we work. Are there questions now, in the field of instrumentation, in the field of units with which radiation is measured, or the potential for real injuries involved?

DR. EDWARD WEBSTER: I think in Dr. Bushong's presentation, there is one rather relevant kind of biological effect which he overlooked, and which I think is very germaine to diagnostic radiology. This is the potential damage suffered by an embroyo during the early stages of pregnancy. There is an important monograph that has been published by Lars Jacobsen indicating that there are significant malformations produced in mice as low as about five rads when the pregnant mouse is irradiated on a specific day, namely, the eighth day after conception. So, I think it isn't right to dismiss immediately the possibility of damage at low doses of radiation.

DR. COLLINS: In asking Dr. Bushong to comment on that, may I add a note of reality to the discussion.

At 2:00 o'clock on next Sunday afternoon, I have an appointment scheduled with a young married couple. It was determined that in the wife's sixth week of pregnancy, she had had a barium enema and an intravenous pyelogram. She's now three months pregnant and is referred to me for an opinion as to what she should do.

DR. BUSHONG: It's a very good point, and one that certainly should not have been omitted.

And it also reminds me of other studies that have been conducted in the same realm, such as the work of Griem in Chicago. Also the recent volume of the Journal of Pediatrics by Yamasaki; and this data indicates essentially what you say; that irradiation early in pregnancy, depending upon the time, can be very significant in terms of affecting the fetus.

DR. ROBERT GORSON: I think we have to be very careful in defining what we mean by the term, "malformation," because whether or not you find malformation depends upon how you define malformation. In our own laboratory, where we have done similar work, we have never been able to find malformation at a level below 25 rads. A part of this may be a difficulty in defining what a malformation is, so I think we have to be very careful when we draw a conclusion concerning the effect of 20 rads or five rads or six rads. We cannot adopt a position unless we define what malformation is.

MR. DAVID TRESSLER: I'm mostly interested in torts with respect to the position with which you are faced, Doctor. Just two weeks ago, a hospital in New Jersey was held liable to the parents on behalf of a malformed child born subsequent to the mother's exposure to measles during her pregnancy. They came to the hospital and asked the doctor where they could go for abortion. The hospital and doctor declined to indicate any doctor who might perform the abortion. The child was born malformed. The parents, on behalf of the child, recovered $10,000 in damages.

DR. COLLINS: That goes to the point of the information presented here this morning. The question is, "What may you reasonably expect a jury to believe?"

DR. CLIFFORD NELSON: Going back to Dr. Bushong's presentation, where he says there was damage caused by five rads of radiation, it wasn't clear whether it was from five rads to the local area or five rads to the whole body. Could someone clarify whether it was a whole body or part of the body that sustained the radiation?

DR. BUSHONG: That was a figure of five rads to a cell. We can say with some certainty that five rads to a cell--for example a leucocyte, or other cultured cell would result in measurable cytogenetic damage. But, I think that's stretching the point, because that's really not the significant question regarding cytogenetic injury.

The significant question in my own mind is this. What is the relationship between the cytogenetic injury--the injury to the chromosomes--and any latent physiological damage manifested at the total body level.

To my knowledge, it is unknown.

MR. ROBERT MALINAK: I'm a lawyer. My question deals with Dr. Brodsky's presentation, specifically with reference to the film badges. I would like to know if the film badges that are used in industry are constructed so that a layman can look at them and determine whether he has been exposed to radiation and if so, to how much?

DR. COLLINS: Dr. Brodsky?

DR. BRODSKY: Well, you can say yes or no. I think the layman has to know a few things before he can tell. One of my slides showed different darkenings of the film from an exposed badge. Any layman can see where the black area is. This film is sensitive to levels of radiation far below the recommended limits for occupational exposure and the exposed area can easily be seen on the film. There's a darkness where it's been exposed.

MR. MALINAK: How soon after exposure would that be indicated?

DR. BRODSKY: Well, you can get the regular development in 30 minutes. In an emergency condition, within a few minutes. It's not too difficult. But, remember the film measures the exposure where the film is located. It is not feasible economically to put film badges all over a person's body. So, part of the management of radiation exposure in health physics is the instruction of the individual to wear the film at the part of the body that would probably receive the maximum radiation.

So, there is a management problem that has developed there. And one thing I want to point out is that there is a lot of emphasis on the errors in dosimetry. And it's really so irrelevant, because as I would like to emphasize, suppose we had a perfect measurement of absorbed energy at every point in time at every point in the body of an individual. Suppose we knew exactly what his dose response relationship was. Suppose it was the year 10,000 A.D. and we knew exactly the dose response relationship for every tissue. I want to say right now, that this is a probabilistic situation. Twenty years from now, if a person got leukemia, we could not say with any authority whether it was due to radiation exposure he received, whether it was due to benzene cleaning fluid his mother might have used when he was a child, or whether it was due to numerous other things, or whether it was a combination of these things that caused the leukemia. I won't get any more complicated at this point or discuss this much further, but I'd like to put that in for the moment.

DR. WEBSTER: Relative to that last point, I think that you have overstated it. I think, for example, if based on a known dose response relationship you could predict how many cases of leukemia would occur with a given amount of radiation that would be very relevant information, and it would probably persuade a jury.

DR. COLLINS: A good point.

DR. BRODSKY: That is a very good point, especially for acute effects of radiation, such as the Gulf incident* you all talk about, the probabilities are high enough, and there is a correlation of so many that it seems to be pretty darn sure that radiation caused these effects. Right.

Let's take a look at what we know about leukemia in a human population. In the Hiroshima-Nagasaki data, which most people believe now, the incidence of leukemia is half a dozen cases. Most people believe this is due probably to radiation, although we haven't heard about the exposure to blast heat and many other traumas at the same time. I believe it was due probably to the initial radiation. However, the incidence rate of one to two per million population--one or two cases per million population per rad of exposure--this is only an average figure. We all know that leukemia really doesn't arise until four or five years later. Therefore, no one single number will give you an incidence rate for a generation.

For example, let's just take ball park figures. Let's talk about the probability of leukemia in the people from the Gulf incident and in the Hiroshima and Nagasaki population. Let's assume a linear curve, which is positive, and a linear extrapolation to zero dose. Say most of these people have had radiation exposure to the bone marrow on the order of 1000 rads. A thousand rads times ten to the minus six gives you one case in a thousand per year of exposure. Say the people live another 10 years, 20 years, 30 years. At the most we would find several cases in a hundred. Even in this very unusual case, where individuals received enough whole body radiation to almost kill them, you still have at the most several cases in a hundred who would develop leukemia. Suppose an individual developed leukemia 20 years after exposure. The probability is only three per cent that it was due to the radiation. Or, you could take the reverse of that and say, "What are the probabilities that this individual may have developed leukemia without the exposure?" There are many other agents.

DR. KARL MORGAN: Just a comment I'd like to make, Dr. Collins, on behalf of the health physicists. I think Drs. Brodsky and Willhoit both have a rather easy job from the standpoint of the health physicist in discussing matters of radiation monitoring and the units of radiation. I'd like to compliment them on their excellent presentations and likewise, Dr. Bushong.

I think the latter speaker had a very difficult job in discussing the response. And here's where we, as health physicists, have difficulty in getting our point over to the medical man. There was one point that Dr. Bushong made that I would like to clarify, or perhaps, disagree with.

In the early part of his presentation, I believe he indicated that there seems to be good evidence of a linear relationship as far as genetic effects are concerned. However, this is not so well-established or so well-clarified, in the case of somatic effects. I think this is true if you are talking about certain types of plants or small organisms and so on, but I think the contrary is less true, if you are talking about mammals and certainly about man.

I think we can show that as far as man is concerned, we have more information to support the linear theory with something like leukemia or thyroid cancer than you have in terms of genetic effects. In fact, looking over the literature this year, I have found a number of papers that give public support to the linear relationship between the dose and the number of thyroid cancers, or between dose and the number of leukemias in man. Several of these papers conclude that this is further evidence of the linear relationship between the gram-rad dose--I like to call that the energy dose--delivered to man, and the somatic effect.

This emphasizes again, I think, what Drs. Brodsky and Willhoit were trying to emphasize; that in many cases, the gram-rad energy dose is the most important. When considering the internal dose problem, it gets even more difficult because you now have two moving targets. For example, if the target organ is bone marrow, then it becomes a function of age in this organ. In this case you have introduced one other moving target; the radionuclide concentration which is a function of time. So, in the case of external radiation, you have the single moving target, the tissue that is irradiated. In the case of internal radiation, you have two parameters that are varying. The problem is really quite difficult. But, I think that we can settle the problem within the parameters that we are seeking to establish here.

DR. JAMES KEREIAKES: I think it's hard to relate what are linear responses and what are threshold responses. For instance, you saw on the curves that Dr. Bushong exhibited that even at zero rads, there is an incidence of leukemia. So, the question becomes, what is the threshold and what is the linear dose response where you normally have an incidence.

PATIENT AND PERSONNEL DOSE DURING DIAGNOSTIC X-RAY EXAMINATIONS

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1. Introduction

The principal purpose of this paper is to discuss the methods available and information required for estimating the radiation dose received by patients undergoing diagnostic x-ray examinations and by persons occupationally exposed to radiation through the administration of such examinations. This topic involves consideration of the extent of commonly available information relating to patient and personnel exposure and its adequacy for dose assessment. However, the methods advocated should be related to the accuracy desirable in such estimates. The desirable accuracy is strongly influenced by the biological significance attributed to the dose and this is usually assumed to be dose-dependent. Dose estimates derivable from data now commonly recorded may then be considered in the light of the desirable accuracy and the need for recording further information, if any should then become apparent.

2. Radiobiological Considerations.

The necessity for recording factors related to personnel or patient dose stems from the belief that radiation exposure may be the cause of a medical disability which arises subsequent to such exposure. Such a disability may occur in the person exposed or to his offspring. In this paper the genetic consequences will not be considered even though it is by no means clear that genetic damage suffered by a parent and exhibited by his offspring cannot be the subject of legal action by that offspring. This Conference specifically relates to the question of disability which is exhibited in the person exposed due to possible effects on his somatic cells.

The dose levels received by persons in connection with x-ray diagnosis are generally less than 10 rads and will hardly ever exceed 100 rads to any tissue. Indeed the mean organ doses per capita per year from this source are almost certainly less than 0.1 rad. Many of the known.effects of radiation on mammals, such as radiation cataractogenesis, erythema, epilation and sterility, may be excluded therefore from consideration. It is not, however, possible to exclude the possibility of the induction of malignancy and in particular, leukemia, in the exposed person. In the case of the female patient who subsequently delivers a child and who was pregnant at the time of exposure, there is also the possibility that malformation of the offspring may be radiation-induced. It is also possible that subsequent development of malignancy in the offspring may be due to radiation exposure *in utero* (1) or due to radiation exposure of either parent *before* the conception of the particular child.(2) Finally, in the case of the occupationally-exposed person, there is the possibility of life-span shortening as a late, non-specific effect. This possibility is considered to be most unlikely in the case of the patient because of the lower doses likely to be received cumulatively and because of the partial-body nature of medical diagnostic exposure. (3)

These possible radiation sequelae are introduced because the radiation doses which may need to be estimated should be those thought to be related to these effects. In the case of the pregnant female it is reasonably certain that the relevant dose is the ovary dose during the early stages of pregnancy and the "mean whole-body dose" to the fetus in the later stages. In the case of malignancy developing following post-natal exposure, it is not known whether the relevant dose which might be associated with such development is that to the tissue in which the malignancy arises, or is that which expresses the total amount of ionizing energy delivered to the body. Specifically, in the case of radiation-induced leukemia, we do not know whether the relevant dose is the peak bone-marrow dose, the mean bone-marrow dose or the mean whole-body dose.

In summary then, several kinds of dose estimate are desirable depending on the nature of the disability which is under consideration:

a) the maximum and mean dose received by the tissue in which the disability occurs;
b) the mean whole-body dose received in utero or post-natally;
c) the ovary dose received by a mother in the early stages of pregnancy.

3. Accuracy required in dose estimates.

The need to establish the doses received by exposed persons derives from the assumption that a probability of a given effect can be assigned which is dose-related. At the present time these relationships for low total doses are either known not at all or only with a considerable degree of uncertainty. However, the prospect of such knowledge cannot be ruled out and then the assembly of dose information would have retrospective importance. This importance will depend on the level of radiation dose involved. If the doses are such that the probability of a medical disability being induced by radiation is small compared to the probability of its development in the absence of radiation, then there will be little legal importance to the exact establishment of the dose. The likely range of the dose should then be established such that the error will not change materially the balance of probabilities as to the cause of the disability. Thus, if the probability of radiation induction is only 1% of the overall induction probability, then a factor of 10 of uncertainty in the dose level will not be important. If, however, the probability of radiation induction is 10%, then a factor of 10 uncertainty should be reduced if at all possible.

As an example, suppose that a child develops leukemia before the age of 10, having been irradiated prenatally in a pelvimetric examination. It is now reasonably well-established that the illness may have been radiation-induced. According to MacMahon (4), as shown in Table I the results of 10 studies are all compatible with an increased risk of leukemia following such irradiation of 40%; specifically, the normal risk of 44 per 100,000 is increased to 62 per 100,000. Hence, on the above findings, of 62 children who were x-rayed in utero and developed leukemia, 18 cases can be attributed to radiation i.e. about 30%. If it is now assumed that the incidence is linearly related to dose, then in the case of a fetus receiving 2.5 times the average level of dose from pelvimetry, there would be an even chance that leukemia was radiation-induced. It would, therefore, seem that in such cases the dose should be known within a factor of two or three.

The work of Graham et al (2), as summarized in Table II, has suggested similar excess leukemia risks for children who have received post-natal diagnostic radiation, particularly where more than one site was irradiated. This

TABLE I

STUDY	CONFIDENCE LIMITS OF RELATIVE RISKS				
	$R-2\sigma$	$R-\sigma$	R	$R+\sigma$	$R+2\sigma$
1. Court-Brown et al.	0.44	0.61	0.85	1.18	1.65
2. Ford et al.	1.07	1.35	1.71	2.16	2.73
3. Kaplan	0.96	1.28	1.72	2.30	3.08
4. Kjeldsberg	0.16	0.31	0.59	1.13	2.17
5. Lewis	0.01	0.08	0.42	2.28	12.4
6. MacMahon	0.99	1.19	1.42	1.70	2.03
7. Murray, et al.	0.24	0.46	0.92	1.78	3.45
8. Polhemus, Koch.	0.89	1.08	1.33	1.63	2.01
9. Stewart et al.	1.24	1.43	1.65	1.90	2.18
10. Wells, Steer	0.22	0.39	0.72	1.32	2.40
Best Estimates, all studies	1.21	1.31	1.42	1.54	1.68

FROM: MacMahon and Hutchison (4)

TABLE II

RELATIVE RISKS OF LEUKEMIA ASSOCIATED WITH POST-NATAL RADIATION OF THE CHILD

Radiation Experience*	Relative Risk	Probability of Risk 1.0
Any post-natal	1.14	0.56
Chest only	1.11	0.77
Extremities only	0.98	0.44
Teeth only	1.42	0.29
More than one site	2.1	0.01
Chest and other sites	2.0	0.03
Abdomen and other sites	1.96	0.19
Extremities and other sites	1.75	0.25
Teeth and other sites	2.8	0.001

*excluding radiation received within 1 year before diagnosis or interview.

FROM: Graham et al (2)

study, if substantiated, would also indicate that it would be important to establish the dose to within a factor of two or three, assuming a linear-dose effect relation.

Again, on the basis of a linear, non-threshold hypothesis, the risk of radiation-induced leukemia in adults has been estimated at about 2 per million per year per rad of whole-body dose. (5) The normal incidence in the U.S.A. is now about 65 per million per year, and of this only a small fraction is attributed to diagnostic radiation since the mean whole-body dose to the population from this source is probably less than 0.1 rad per year. Hence, after receiving 1 rad of whole-body radiation, there appears to be 1 chance in 30 that subsequent leukemia is radiation-induced. Therefore, if the whole-body dose in a given case were estimated at 0.1 rad, an error in the estimate by a factor of 10 would not materially affect the conclusion that the illness was not induced by radiation. However, if the dose estimate was 1 rad instead of a true value of 10 rad, the correction of such an error would change the probability from a 1 in 30 chance to a 1 in 3 chance that the disease was radiation-induced. Mean doses to the active bone marrow of the order of 10 rads are possible from diagnostic radiology. Dose estimates in adults which might be as high as 10 rads should, therefore, be refined if possible to uncertainties of a factor of 2 or 3. The requirement of this accuracy will not depend on this dose level for any one film or exam, since the probability of radiation-induced illness is assumed to depend on the total dose; at the time of any one exam the total radiation experience of the subject will probably not be known, and his future experience uncertain. Therefore, an accuracy of dose estimation within a factor of 2 or 3 is desirable for all examinations which may contribute bone-marrow doses of the order of 1 rad.

The information needed to estimate doses in patients and in occupationally-exposed persons are rather different and, therefore, these discussions are presented in two separate parts A and B in the following.

A. Patient Dose

A1. Determination of Patient Dose

Whether one is considering skin dose, dose to other structures in the useful beam, dose to structures outside the useful beam, mean bone marrow dose or mean whole body dose, there are a great many variables which affect these values. Some of these are patient variables such as size and shape; some are x-ray source operating variables, such as peak kilovoltage, tube current, exposure time, total filtration, source-skin distance and tube voltage waveform; some are operator variables such as field size, alignment of x-ray source with target organ, number of films taken and time of fluoroscopy; some are recording and processing variables, such as type of Bucky grid, film, intensifying screens and developer, the time, temperature and age of the developer. Although these factors affect the dose delivered per examination, some of them are inter-related so that it is not necessary to know all of them in order to estimate the dose. Thus, the use of a faster film-screen combination will be reflected in smaller exposures in milliampere-seconds or lower peak kilovoltages, while an increase in focus-film distance has the opposite effect.

There are two physical ways to estimate the dose in radiography, one of which starts with the x-ray source while the other starts at the film. Of these the former is the simpler.

A2. Use of X-Ray Exposure Factors in Radiography.

The dose and its distribution through the patient is most fundamentally determined by the amount of x-ray energy that leaves the collimator of the x-ray tube. This amount of energy can be measured and as discussed later, has great usefulness; it does not, however, by itself indicate the absorbed dose to any part of the body. Moreover, it is yet rather rare to find installations equipped for this measurement. It is probably more practical at present to work from other recorded data.

a) Skin dose. While the skin dose may have little biological long-term significance, it forms a convenient starting point for dose estimates. The skin dose has a well-defined relationship to the peak kilovoltage of the x-ray tube, to the total filtration, to the voltage waveform, and to the focus-skin distance. It has rather little dependence under diagnostic x-ray conditions on the field size, but this dependence is known. The nomogram given in Fig. 1 is derived from data for a full-wave rectified waveform which is presented in NCRP Report No. 33.(6) Backscatter factors

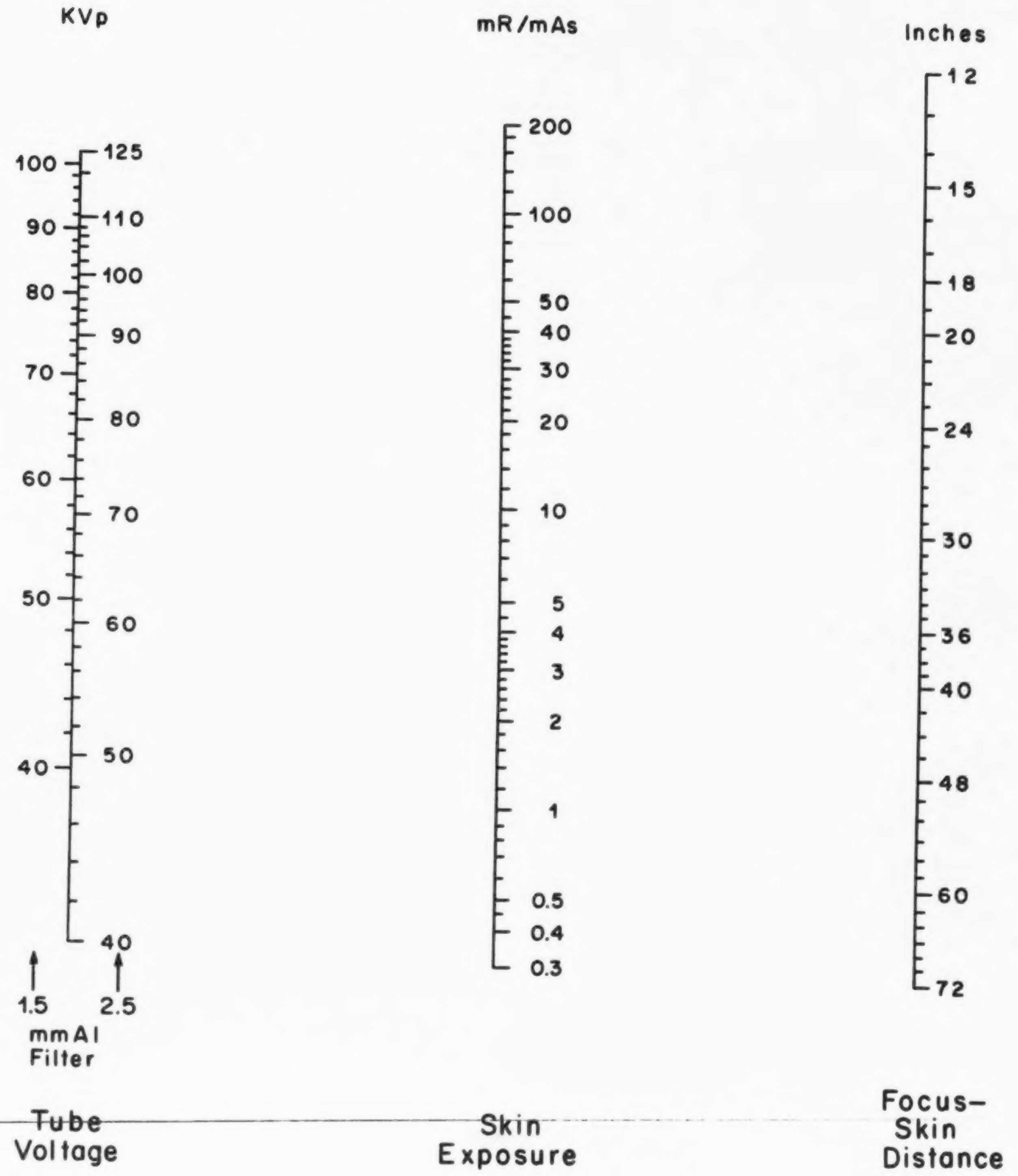


Figure 1. Nomogram for estimation of skin exposure (full-wave rectified waveform)

measured by Trout (7) for a 14" x 17" film size at 40" focus-film distance have been applied to the air exposures. The data are for two common total filtrations, 2.5 mm Al and 1.5 mm Al; factors for other filtrations can be derived from Report No. 33 and from Trout (8). The use of 3-phase or constant potential equipment approximately doubles the skin dose for a given set of physical factors.

The errors in skin dose estimation from these factors stem largely from uncertainties in the true value of these factors; for example, the total filtration may not be known, although it can be deduced from measurements of half-value layer, and there may be considerable discrepancies between the indicated and actual value of the peak kilovoltage and the tube current. Generally these uncertainties do not result in errors exceeding 50%.

b) Depth Dose The dose to structures in the useful beam can be derived by applying depth dose information obtainable from the literature. This information is usually presented as a percentage of the skin dose. Most of this data is for the central axis, but Trout, Kelley and Lucas (7) have published an assortment of depth dose charts for 8" x 10" and 14" x 17" fields (at 40" FFD), which provide off-axis information for beams generated at 40 kVp to 150 kVp. The dose to a given structure will depend on its depth below the skin and its distance from the axis; information on both the patient thickness and the field size is therefore required.

c) Doses outside the useful beam. The doses of major biologic importance are those to structures in the useful beam. However, where the ovaries are a critical tissue (in dose estimates during early pregnancy) the dose due to scatter may be of interest. This has been investigated by Haybittle (9), who has shown that the dose falls exponentially with distance from the edge of the beam by a factor of about 10 for every 5 cm of distance and that this rate is nearly independent of field size and of kilovoltage from 60 to 120 kVp.

d) Dose to bone marrow. Dose to the bone marrow is difficult to calculate from skin dose and depth dose data because of the further detailed knowledge required of the depth, location in the field and amount of active marrow and degree of shielding by cortical bone at each location. Estimates must be based on the results of empirical studies such as those of Epp et al (10) (11) who give the distribution and average value of bone marrow dose for several examinations imparting high doses (pelvis, hip and spine) and for chest examinations. The variables considered are tube kilovoltage, field size and added filtration and the data is presented in mR per mAs.

e) Integral dose. On the assumption that all the energy leaving the x-ray tube collimator is absorbed in the body, the integral dose may be estimated from air exposure data, field size and mean photon energy in the useful beam. However, this quantity may be more simply and more accurately derived experimentally by installing a special ionization chamber near the collimator exit. Designs have been described by Reinsma (12) and Gehret (13), the former instrument giving values in kilogram-rad units and the latter in millijoules. These are related units: 1 kg-rad = 10 millijoules.

The integral dose may be converted into a mean whole body dose in rads by dividing by the body mass. This should have some relationship to the observed incidence of chromosomal changes in blood cells and may correlate with the incidence of leukemia or other malignancies in exposed persons.

A3. Use of Film Density Measurements in Radiography.

One of the records of a radiographic examination which is often available is the radiograph. This may provide some significant information with respect to the evaluation of the patient dose, particularly the field size if the margins of the field are in evidence, and the incident exposure in roentgens if there is a region of exposure where the beam did not pass through the body. The usefulness of the film as a dosimeter is, however, quite limited since a considerable amount of ancillary information is required, some of which is practically unattainable. The type of film and screen is usually known since few varieties are in use in any one establishment. It is also possible to discover the "speed" of the film or film-screen combination for the method of film processing recommended by the manufacturer. The speed is the reciprocal of the exposure in roentgens required to produce a density of unity above the fog and base density. The actual exposure of the film in roentgens requires access to the H and D curve for the film, or at the least the film gamma. It would be helpful if such information were included by the film manufacturer with each batch of film. However, the speed rating will vary substantially with the developer, the time and temperature used (14), (15), the depletion of the developer, and in the case of screen-film combinations, with the quality of the incident radiation.(16) These variations may lead to an uncertainty by a factor of at least two in either direction.

In order to determine the patient exit dose from the mean film exposure it is necessary to know the characteristics of the Bucky grid, if one is employed; specifically its grid ratio and preferably its weight per unit area. The effect of the grid in modifying the exit dose by removal of scattered radiation depends not only on the grid characteristics, but also on the field size, patient thickness and peak kilovoltage of the x-ray beam. Such information is difficult to obtain, but may be estimated from Bonenkamp and Boldingh (17).

The entry skin dose of the patient may be determined from the exit dose through the application of depth dose data already discussed.

If the film shows an area of exposure due to unattenuated primary radiation, reference to the H and D curve for the recording system will provide an estimate of the exposure in roentgens at the film from which the air exposure at the entry skin of the patient may be computed. Failing this, it is concluded that the preferable method to estimate patient doses in radiography is to utilize known technique factors: kVp, mAs, filtration, waveform, field size and distance.

A4. Use of X-ray Exposure Factors in Fluoroscopy.

The dynamic nature of fluoroscopy renders the estimation of patient dose, even to the skin, much more uncertain than in radiography. In conventional fluoroscopes and in most units which employ image intensification, examinations are performed with values of peak kilovoltage and tube current which are fixed for that examination. Most fluoroscopes are also equipped with cumulative timers and indeed this requirement is mandatory in the recommendations of the NCRP (Report No. 33). (6) From further knowledge of the total filtration and tube-skin distance it would be possible to estimate the skin dose (and thence doses to organs in the useful beam) for a given examination following the radiographic method, if the useful beam were fixed in size and location. However, the beam is not so fixed; both the location and the beam size are highly variable in a manner which depends on the operator and on the nature of the examination. Under these circumstances, the fraction of the exposure of a given organ can only be an educated guess based on knowledge of the operator's normal examination practice. Film has been used to study the dose distribution at the surface of patients undergoing typical fluoroscopic examinations, and to illustrate the individual variability.

The problems of estimating patient dose are even more complicated in apparatus employing automatic brightness control, since the exposure factors will vary throughout an examination with the thickness and opacity of the body and with the field size. It is not practical to record these factors. Automatic brightness control is universally used in cinefluorography. Here there are further physical variables which affect patient dose such as the frame rate, the speed of film used and the film size. It is possible to derive average input exposure rates for a given apparatus by calibrating it for a range of phantom thicknesses, using multiplying factors for the other variables listed above. It must be emphasized that such calibration should be performed on a regular schedule in order to take account of the deterioration of the brightness gain which may occur with continued use.

Under the above circumstances a significant index of patient exposure will result from the use of an integral dose recording device on the x-ray tube between the collimator and the patient. It is likely that data on this quantity can be correlated with mean bone marrow dose for different ages and size of patient and for different types of examinations. Information on the range of the integral dose has been published by Reinsma (12) and Morgan (18). Morgan has drawn attention to the great spread in integral dose which may occur between an experienced radiologist, a radiological resident and non-radiologist physicians performing similar examinations. Thus, fluoroscopy of the colon, including spot-films, may require an integral dose of 10-40 kg-rad when performed by a radiologist, and 20-150 kg-rad when performed by a resident or non-radiologist. (19) Reinsma quotes a similar spread for a colon examination (including radiography) from 32 to 178 kg-rad. (12)

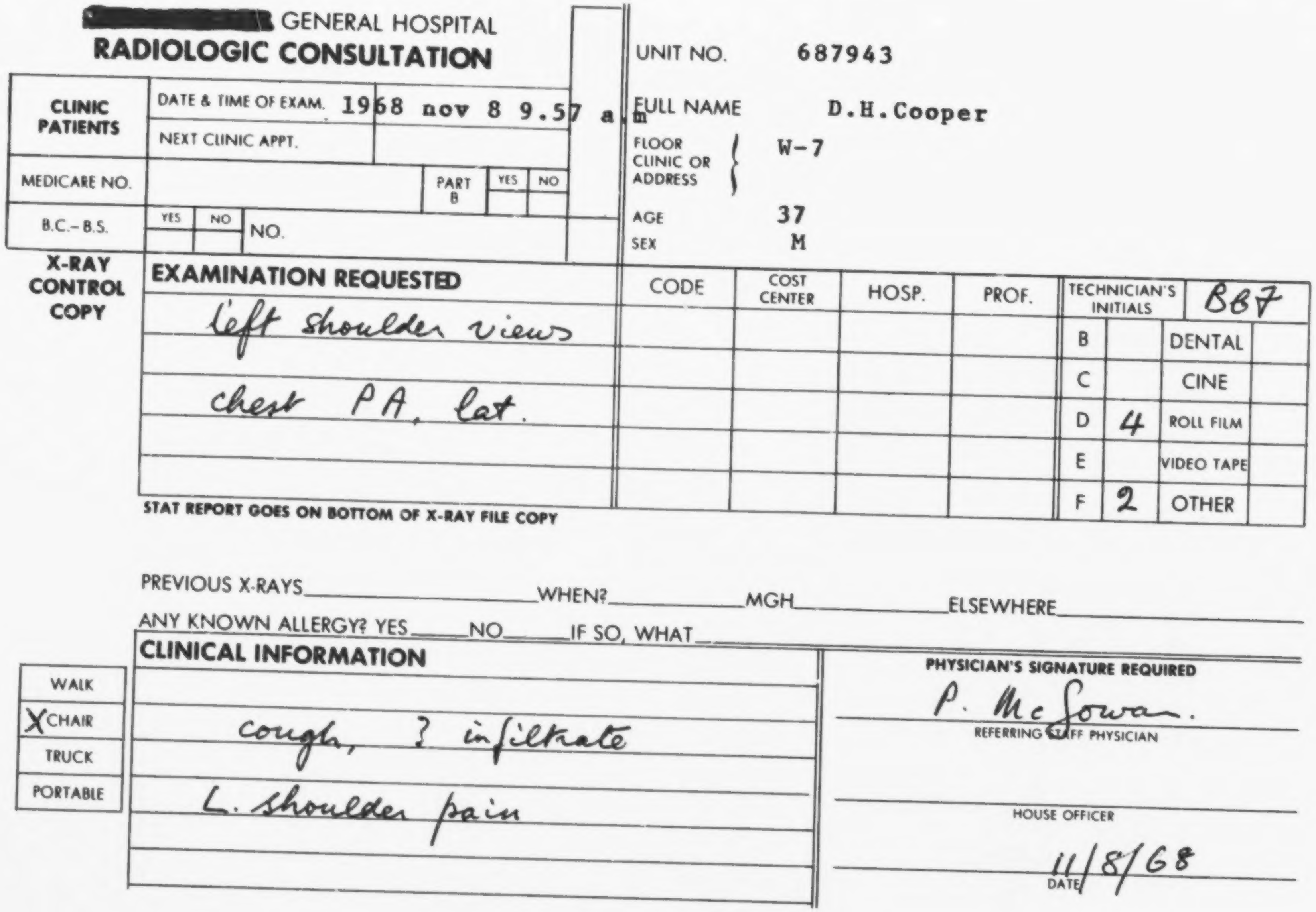
A5. Data in the patient record relating to x-ray exposure

Information with regard to a radiodiagnostic examination is recorded during several phases of such an examination. The extent and final disposition of such information varies between medical centers or medical offices. Here the procedures in the Department of Radiology in a large general hospital will be quoted as typical.

The procedure is started by the referring physician who will request an examination specifying the anatomic region or the title of the examination and brief clinical reasons for it. Such a request is shown in Fig. 2. This request is carried on several attached carbon copies and also on the attached form for reporting the results of the examination.

The technician who performs the examination completes and initials the technique section which appears on these forms. The only information recorded is the number of radiographic films taken of each size, with an indication of whether a more advanced modality such as cinefluorography was used. The original copy of this information is attached to a copy of the radiologist's report which is used for billing purposes.

The radiologist receives the request and report forms with the films and makes his report. The report will indicate whether fluoroscopy was performed and the general region examined. The fact that spot-films were taken will also usually be evident from the report, a typical example of which is shown in Fig. 3. One copy of the report is returned to the patient's record; one copy is retained for billing purposes; and a final copy is filed in an envelope containing all the extant patient's films. This envelope carries a listing on the outside of all the patient's films, using the data recorded by the technician to update the record with each new examination. An example of this is shown in Fig. 4.



[redacted] GENERAL HOSPITAL
RADIOLOGIC CONSULTATION

CLINIC PATIENTS	DATE & TIME OF EXAM. 1968 nov 8 9.57 a.m	UNIT NO.	687943
	NEXT CLINIC APPT.	FULL NAME	D.H.Cooper
MEDICARE NO.	PART B YES ☐ NO ☐	FLOOR CLINIC OR ADDRESS	W-7
B.C.–B.S.	YES ☐ NO ☐ NO.	AGE	37
		SEX	M

X-RAY CONTROL COPY

EXAMINATION REQUESTED	CODE	COST CENTER	HOSP.	PROF.	TECHNICIAN'S INITIALS	BB7	
left shoulder views					B		DENTAL
chest PA, lat.					C		CINE
					D	4	ROLL FILM
					E		VIDEO TAPE
					F	2	OTHER

STAT REPORT GOES ON BOTTOM OF X-RAY FILE COPY

PREVIOUS X-RAYS____ WHEN?____ MGH____ ELSEWHERE____

ANY KNOWN ALLERGY? YES____ NO____ IF SO, WHAT____

WALK
X CHAIR
TRUCK
PORTABLE

CLINICAL INFORMATION

cough, ? infiltrate

L. shoulder pain

PHYSICIAN'S SIGNATURE REQUIRED

P. McGowan.
REFERRING STAFF PHYSICIAN

HOUSE OFFICER

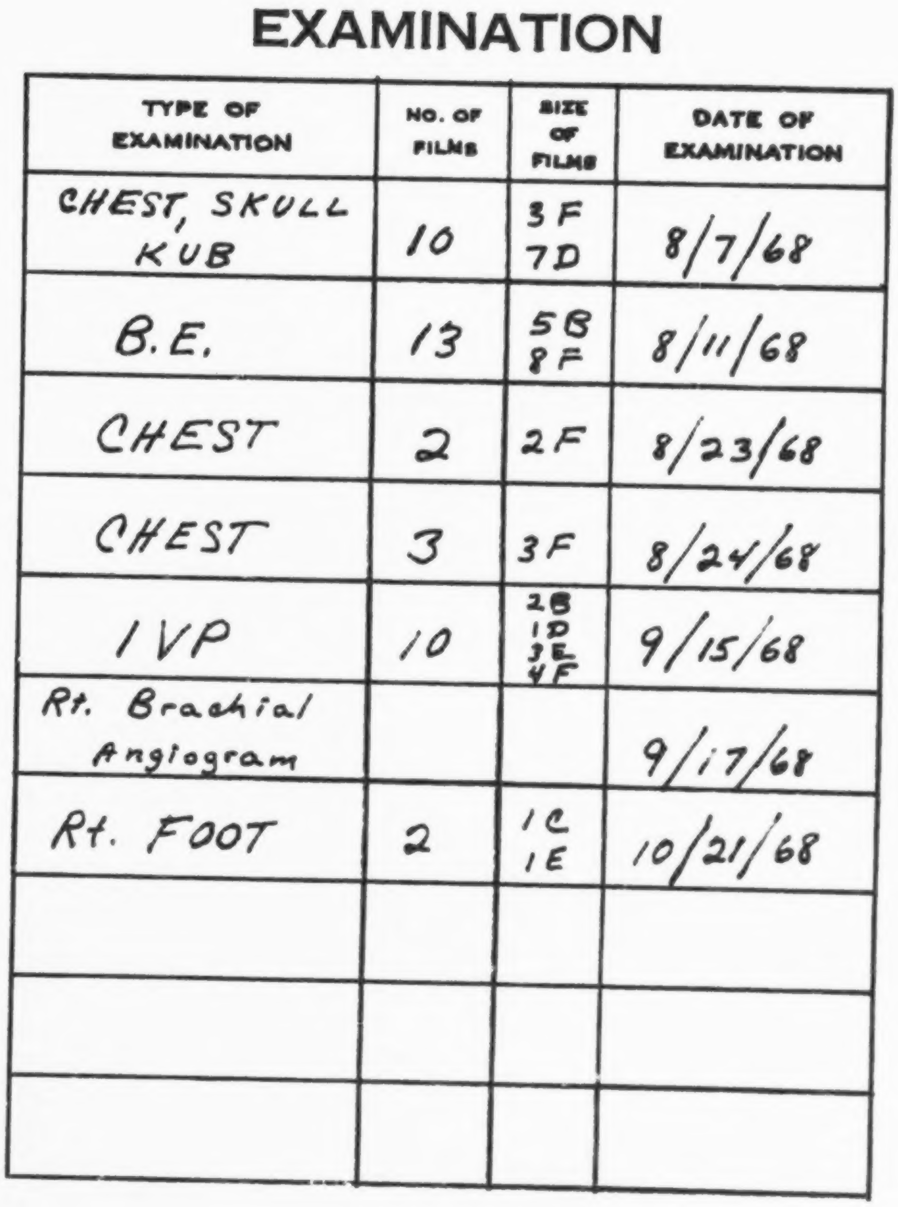
11/8/68
DATE

Figure 2. Request for X-ray examination and technician's record

7/19/68: BARIUM ENEMA: A preliminary plain film of the abdomen does not demonstrate any obvious abnormality. Barium passed normally retrograde fashion from the rectum around to the cecum. There was an area of narrowing in the region of the descending colon adjacent to the beginning of the sigmoid colon. This area is approximately 3 cm. in length, but during multiple spot films the mucosa is seen to be preserved. Also the narrowing does change in distensibility. On later films there is noted to be a sinus tract from this narrowed area extending out anteriorly through the fistula on the anterior abdominal wall in the midline. Occasional diverticuli are noted in the area, as well as in the region of the splenic flexure as well. No other abnormal intrinsic or extrinsic colonic masses are noted, and on the post-evacuation film no further abnormalities are evident. In view of the distensibility as well as the preservation of the colonic mucosa, the area of narrowing and fistula is felt to represent a perforated diverticulum, and perhaps in view of the history this was an area of previous diverticulitis in this patient.

IMPRESSION: Fistula with sinus tract to anterior abdominal wall, probably due to perforation from previous diverticulitis.

Figure 3. Typical diagnostic X-ray report



EXAMINATION

TYPE OF EXAMINATION	NO. OF FILMS	SIZE OF FILMS	DATE OF EXAMINATION
CHEST, SKULL KUB	10	3F 7D	8/7/68
B.E.	13	5B 8F	8/11/68
CHEST	2	2F	8/23/68
CHEST	3	3F	8/24/68
IVP	10	2B 1D 3E 4F	9/15/68
Rt. Brachial Angiogram			9/17/68
Rt. FOOT	2	1C 1E	10/21/68

Figure 4. Typical film record on storage envelope

The original technician's entry of the number of films has a relatively short life, since it is destroyed when the charge for the examination is settled. This information persists, however, in the film files until they are destroyed. This time is quite variable in different medical enterprises but the policy at this particular general hospital is to destroy the films and the filed listing 5 years after the last recorded access to those films on behalf of the patient. After that time the information remaining is in the patient's record and contains the radiologist's report and an uncertain carbon copy of the technician's entry regarding the number of films.

A6. Patient Dose Estimates from Existing Records.

From the above it will be recognized that apart from the films themselves, the information available typically consists of the type of examination performed (including the fact of fluoroscopy) and possibly the number of films of each size which were taken. The extent of the examination may not be fully known since:

a) the technician will not usually record the films which were rejected because they were immediately recognized as unsatisfactory,
b) the radiologist may dispose of certain films which he considers worthless,
c) in certain special examinations the number of exposures made is not usually recorded -- e.g. the total number of films in an angiographic procedure, or the amount of roll film used; the total time of a cinefluorographic run; the number of cuts made in a laminographic examination.

The technical factors employed for the specific examination are usually not recorded. Retrospective investigation may indicate the typical factors for the examination at the time of examination and allowance may be made for patient size deduced from the medical record, but there may be some uncertainty in these factors since, in an establishment containing more than one x-ray unit it may not be known which unit was used and the factors in use may be rather different on different units. However, fortunately, the film itself (assuming that the same recording system is used in the competing rooms) will serve to reconcile the different sets of exposure factors which are usually chosen to produce comparable film densities and therefore may produce closely similar patient doses.

If the x-ray exposure factors used cannot be established then an estimate of patient dose based on skin dose or on film density cannot be made, except in the case where the unattenuated useful beam is recorded on the film. An important technical factor which frequently cannot be established with certainty is the field size used. Usually a minimum estimate is provided by the film size used, unless the field borders are contained in the exposed film. The field size, however, frequently exceeds the film size. Fig. 5, taken from a report of the U.S. Public Health Service, indicates that in non-radiologic x-ray practice of the field area is frequently 4 times the area of the film. Lack of knowledge of this factor introduces a very large uncertainty into estimates of dose to tissues outside the immediate area recorded on the film - e.g. a factor of 100 depending on whether the tissue was in the useful beam or 4" outside the useful beam.

On the basis that only the number of films taken is known, a crude estimate of dose can be made on the basis of published x-ray factors for recommended radiographic techniques and collections of dose data for examinations using such techniques. Such dose data are available for skin dose, gonad dose and to a more limited extent, bone marrow dose. The skin dose data are in fair agreement and a sample table taken from Webster and Merrill (20) is given in Table III. On the other hand, measurements of gonad dose are often in wide disagreement between different authors in the same country and between different countries. This divergence is illustrated in Table IV which presents average ovary doses in adult females determined in national studies in four countries. (21,22,23,24) Thus, the typical examination of the hip in Denmark resulted in more than 10 times the average dose given in the United Kingdom; and the gallbladder examination in the United Kingdom resulted in about 17 times the average dose given in the U.S.A.

There is relatively little information available on mean bone marrow dose per examination. In Table V typical doses measured in the U.S.A. by Epp et al (10) (11) for a few examinations are compared with doses per examination averaged for adult examinations in Denmark (25) the United Kingdom (26), and the Netherlands (27). It will be noted that there are factors of 4 to 8 between the dose estimates for several examinations performed in different countries.

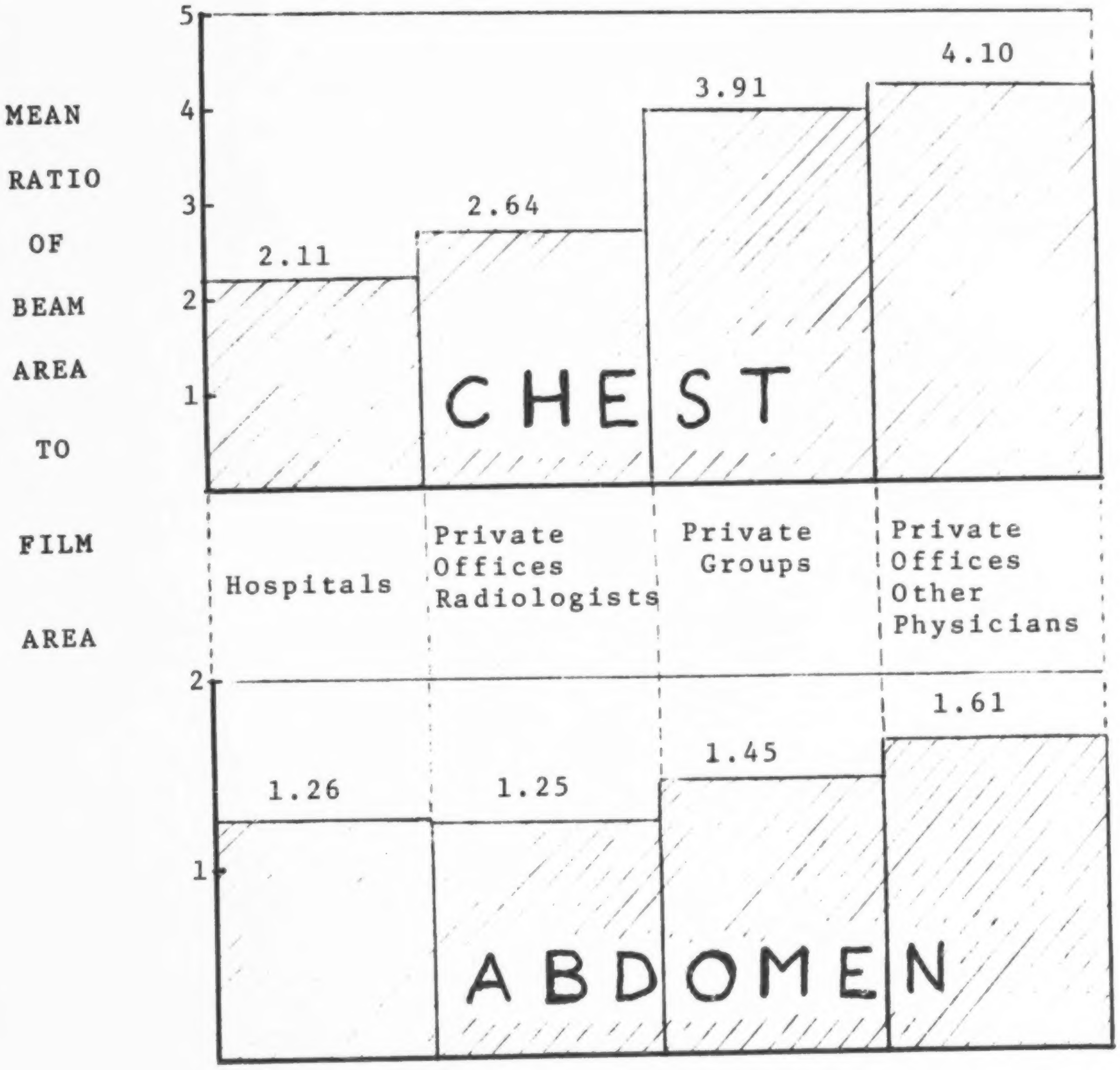


Figure 5.-Estimated Mean Ratio of Beam Area to Film Area for Selected Radiographic Examinations by Type of Facility, U.S., 1964.

(Penfil and Brown, Radiology, 1968)

TABLE III

TYPICAL X-RAY FACTORS AND SKIN DOSE IN RADIOGRAPHY

Examination	View	kV	MAS	FFD inches	Skin Dose R
Skull	AP	68	60	36	0.6
	Lat.	58	60	"	0.3
	Basal	76	60	"	0.8
Shoulder	AP	68	20	"	0.2
	Lat.	80	100	"	2.0
Chest	PA	86	10	72	0.02
	Lat.	90	30	"	0.07
Abdomen	AP	72	60	36	0.6
Gallbladder	PA,scout	72	60	"	0.6
	PA, spot	78	60	"	0.7
	Lat.decub.	72	60	"	0.6
IVP	KUB, AP	72	60	"	0.6
	Kidneys,AP	72	60	"	0.6
Bladder	AP	72	60	"	0.6
	Lat.	85	400	"	7.7
Upper G.I.	PA	72	90	40	0.9
	Lat.	80	150	"	2.1
Lower G.I.	PA	72	90	"	0.9
	Lat.	84	150	"	2.5
Cervical Spine	AP	64	20	36	0.16
	Lat.	75	10	72	0.04
Thoracic Spine	AP	74	50	36	0.6
	Lat.	80	80	"	1.5
Lumbar Spine	AP	70	80	"	0.85
	Lat.	80	150	"	2.9
Pelvis	AP	66	70	"	0.65
Hip	Lat.	75	150	"	2.3
Femur, lower two-thirds	AP	68	50	"	0.5
Knee	AP, Lat.	55	10	"	0.04
Leg, lower NS	AP, Lat.	60	100	"	0.5
Foot, NS	AP, Lat.	56	50	"	0.17
Ankle, N.S.	AP, Lat.	60	100	"	0.5
Elbow, Arm,	NS	55	100	"	0.4
Hand, NS		50	50	"	0.12

TABLE IV

OVARY DOSES PER RADIOGRAPHIC EXAMINATIONS IN ADULTS

Examination	(21) Denmark mR	(22) Sweden mR	(23) U.K. mR	(24) U.S.A. mR
Head	3.7	0.5	1.9	4
Chest 14" x 17"	4.6	4.1	5.5	8
Chest, miniature	17	1.8	0.1	8
Cervical Spine	1.0	-	1.9	2
Dorsal Spine	7.8	6.2	11.7	9
Lumbar Spine	321	480	405	275
Pelvis	302	200	405	41
Hip	1322	260	117	309
Femur	168	35	7.3	1
Gallbladder	74	193	299	17
Abdomen	222	1150	212	289
IVP	744	925	637	407
Upper G.I.	97	29	339	-
Lower G.I.	699	1520	464	-
Cystography	1444	1940	1285	-

TABLE V

MEAN MARROW DOSES PER RADIOGRAPHIC EXAMINATION IN ADULTS

Examination	(25) Denmark mR	(26) U.K. mR	(27) Netherlands mR	(10,11) U.S.A. mR
Head	-	36	90	-
Chest 14" x 17"	20	12.5	10	15
Cervical Spine	-	51	8	9
Dorsal Spine	200	208	105	134
Lumbar Spine	100	270	140	330
Pelvis	30	136	138	42
Hip (upper femur)	20	59	47	35
Gallbladder	150	148	36	-
Abdomen	30	126	93	-
IVP	80	518	433	-
Upper G.I.	200	652	80	-
Lower G.I.	200	795	359	-
Cystography	-	557	168	-

However, not only are the published estimates of mean bone marrow and gonad doses for the average adult variable by a factor of 4; the individual variations in a given hospital of dose in a particular exam are also very great. Table VI is due to Reinsma (12) and records the integral dose for several examinations according to the range from maximum to minimum. In high dose examinations, where it is more important to know the dose with some accuracy, the range covers a factor of 6 or more.

It is therefore concluded that the general application of published average data on patient dose could readily lead to errors by a factor of 4 in either direction in patient dose. In many situations, for example, where a large but unspecified amount of fluoroscopy was performed, the underestimate of dose could reach a factor of 10 or more, in terms of skin dose, integral dose, bone marrow dose or specific organ dose.

A7. Are Present Medical Records adequate for estimates of Patient Dose?

It has been pointed out that the content of the medical record is variable: for example, in some medical facilities the x-ray films taken may not be available after the lapse of a few years. If it is assumed that the films are not available then generally the patient record will only indicate the type of examination which was performed, including fluoroscopy and possibly the number and size of films which were taken. Estimates of patient dose can then be made through considerable investigation based on the availability or recall of technique charts which were in use at the time of the examination, on the knowledge of the type of equipment in use (screens, films, cones or collimators), on the typical practice of the technicians working in the facility at that time, on recorded performance data of equipment such as radiographic and fluoroscopic units (filtration, exposures for given sets of technical factors), and on the typical practice of the radiologist. Consideration of these factors might result in dose estimates to those tissues receiving maximal exposures which were correct to within a factor of 4. The greatest uncertainties would be in connection with fluoroscopic dose.

Dose estimates based on the number of films taken and the type of examination without further investigation could well be in error by a factor of 10.

TABLE VI

RANGE OF INTEGRAL DOSE IN DIAGNOSTIC X-RAY EXAMINATIONS

Rotating anode tube, peak kilovoltage 125

Inherent filter: 1 mm Al

Added filter: zero or 0.05 mm Cu + 1 mm Al

Region Examined	No. of Patients	Integral dose in kg-rad		
		min.	max.	average
Thorax	219	0.3	30.4	5.6
Stomach	95	9.4	146.7	34.8
Gallbladder	67	0.7	50.1	11.2
Cervical vertebrae	21	1.0	10.9	5.1
Colon	15	32.1	178.6	96.8
Stomach/Intestinal canal	12	47.3	248.8	106.6
Esophagus	6	7.4	33.4	18.7

From: Reinsma (12)

Because x-ray examinations might produce doses to critical tissues of the order of 10 rads and because these doses may confer a credible probability that subsequent development of leukemia (and possibly other malignancies) was radiation-induced, it is important that greater accuracy in retrospective dose estimation should be developed. It is, therefore, suggested that the patient record should include certain presently available data and that in addition certain measurements which are not presently made should be made and recorded routinely in the future. Specifically it is recommended that the record should note all exposed films which were taken, together with at least the peak kilovoltage, voltage waveform, mAs, target-film distance and field size at that distance, for each exposure. The recording of filtration, although desirable, is not suggested since its influence on the integral dose and dose to deep tissues is relatively small. (12) In fluoroscopy the kilovoltage, tube current and total fluoroscopy time should be recorded together with the number of spot-films and the kilovoltage and exposure in milliampere-seconds used for them. In confirmation of part of these data the integral dose for each exposure or for each examination should be measured and recorded.

The single act of installing an integral dosimeter and routinely recording its readings will provide dosimetrically important information, possibly the most significant from the standpoint of long-term somatic effect, if used properly. Of course, the interpretation of the readings of such a device depends on the extent to which the useful beam is absorbed in the body tissues. In the trunk of the body almost complete absorption should be easy to arrange. The continuing use of such a device produces a salutary effect on the conduct of radiological examinations (18). The unit cost of such a device is approximately $1500, and it is suggested that it should be standard equipment.

B. Personnel Dose

B1. Nature of Exposures

Personnel exposure to diagnostic radiation is probably more difficult to assign accurately than is patient exposure. This is because the physical factors causing the exposure are quite variable and the circumstances of the exposure are uncontrolled. Even though a dose recording device is usually carried to "monitor" personnel exposure, the actual exposure of the person may not be known because the distribution of the radiation field in space is usually uncertain and can only be estimated from knowledge of the likely circumstances of the exposure.

In diagnostic radiology, exposure of personnel usually occurs from scattered radiation. Providing the distance of the person from the radiation source or scatterer is similar to or greater than the dimensions of the body i.e. 6 ft or more, then the distribution of scattered radiation in space is fairly uniform. However, the distribution of radiation incident on the body may not be so uniform because of the presence of radiation shielding which will absorb the great majority of the radiation energy. Occasionally exposure occurs accidentally to the useful beam. Typically fields are used which are approximately 1 foot in dimension at a distance of 3 feet from the tube target. Hence, under these circumstances the radiation field will be relatively uniform only at distances comparable with room dimensions. Under these circumstances the dose measured by a personnel monitoring instrument may be considered to be dose incident on the person.

In diagnostic radiology the most usual source of personnel exposure is fluoroscopy since this is the principal procedure which requires the presence of personnel near the x-ray source and the patient. With a fluoroscope in the horizontal position the exposure rate due to scattered radiation has values ranging from 100 to 1000 mR/hour over a region at the side of the table about 1 foot high between the table-top and the holder for the fluoroscopic screen or image intensifier. Frequently there is also a second band of high exposure rate next to the slot for the Bucky grid tray. Above and below these regions the exposure rate falls rapidly to values of only a few mR/hour. Hence, the radiation field is quite non-uniform.

B2. Personnel Exposure Records

Even though it is permissible under many radiation protection codes for occupationally-exposed personnel likely to receive less than 25% of the maximum permissible dose to be exempted from the requirement of personnel monitoring, this exemption is rarely practiced. One reason is the possibility of accidental exposure to single partial-body exposures approaching 1 roentgen; another is the desire to monitor the working habits of personnel in respect of protective measures.

Personnel exposures are routinely recorded as the readings of personnel dosimeters which are usually film badges but sometimes ionization chambers and more recently thermoluminescent dosimeters. These devices are calibrated with radiation of a quality typical of that expected in personnel exposures. In the case of dosimeters which show appreciable energy dependence, a filter system is usually incorporated which will indicate through differential readings under each filter the quality of the radiation responsible for a given dosimeter exposure. Although the dosimeter readings are recorded, it is quite certain in the case of diagnostic x-rays that these readings do not represent the biologically significant dose to the wearer.

B3. Differences between recorded personnel dose and biologically significant dose.

The "biologically significant" dose for personnel is similar in meaning to that for patients, and includes: a) the dose to tissues which may be associated with the development of malignancy, the principal example of which is the bone marrow; and b) the dose to other critical organs such as the ovaries in potentially pregnant female personnel; and c) the mean dose to the whole body which may be associated with non-specific effects such as lifespan shortening.

There are several reasons why the conventionally recorded personnel "dose" is different and usually much higher than the above biological doses.

1. There are uncertainties in the exposure recorded by the dosimeter due to technical factors. These reasons often operate to make the recorded dose somewhat lower than that actually received.

   i) In the diagnostic range of x-ray photon energy, the response of the dosimeter is usually markedly energy dependent. In the case of film, increase of photon energy reduces the density response to a given exposure. The dosimeter is often calibrated by radiation which has a different spectral distribution from that incident on the person. For example, if the dosimeter is calibrated with the useful beam of x-rays from a diagnostic x-ray tube, this beam is likely to be considerably softer than the scattered radiation encountered near a fluoroscope and softer still than the radiation which penetrates a lead apron. In this event the personnel exposure will be greater than that apparent from the dosimeter calibration.

ii) The dosimeter carried by a person is exposed by radiation which will arrive from a considerable range of direction. The response of the dosimeter usually shows some directional dependence. Again, in the case of a film badge, radiation arriving from an off-normal direction will produce a lower response than radiation arriving normally (28). Since the badge is usually calibrated with normally-incident radiation, the true exposure of a badge carried by a person will be larger than the apparent exposure.

iii) Some dosimeters, particularly ionization chambers, exhibit a dose-rate dependence at high rates. This dependence may cause an exposure received at a high rate (for example, close to the target of a diagnostic x-ray tube) to be evaluated as a lower exposure.

iv) The response of a dosimeter may "fade" over a period of time following its exposure. On the other hand, ionization chambers may discharge gradually through electrical leakage, so that the apparent exposure is greater than the actual exposure.

2. There are uncertainties in personnel skin exposure as related to the dosimeter exposure.

   i) In diagnostic radiology the dosimeter is usually in a markedly non-uniform field. Depending on where the dosimeter is worn, the mean incident exposure may be more or less than the recorded exposure. Close to a fluoroscopy a dosimeter worn at the waist by an unshielded person may read several times the exposure received by the skin over the upper chest.

ii) The wearing of protective clothing by personnel greatly changes the distribution of the radiation incident on the body, so that the recorded dose may not he representative of the skin dose most relevant to the biologically significant organs. Table VII shows the exposure recorded on film badges worn in two locations on the body by radiologists fluoroscoping with image intensifier equipment.(30) Badges were worn at the collar above a lead apron 0.5 mm thick and at the waist level under the apron. On the average the exposure recorded at the collar was about 3 times the exposure recorded at the waist. If a badge had been worn on the outside of the apron at waist level it would have been recorded about 30 times more dose than when under the apron.

3. There are uncertainties in the critical organ dose as related to the skin dose.

   i) The dose to critical organ is very much less from diagnostic radiation than the dose to the skin. Typically, for a large field of well-filtered diagnostic x-rays of half-value layer about 5 mm Al, the depth dose at 10 cm. below the skin is about 30%. (7) The measurements of Epp et al (11) of bone marrow doses from diagnostic x-ray exposures of the abdomen indicate peak bone marrow doses of about 60% of the skin dose and mean bone marrow doses of about 10% of the skin dose.

   ii) The non-uniformity of the field incident on the body may cause the mean whole body dose to be an even smaller fraction than those noted above of the maximum skin dose which it is assumed is recorded by a personnel dosimeter. Assuming that, for example, only half the trunk receives the recorded skin dose then the mean whole body dose will be perhaps 8% of the recorded skin dose due to well-filtered diagnostic x-rays with a half-value layer of 5 mm Al.

TABLE VII

X-RAY EXPOSURE OF RADIOLOGISTS IN FLUOROSCOPY USING IMAGE INTENSIFIERS (30)

	Milliroentgens per Month								
Radiologist	A				B				C
Waist level, below 0.5 mm apron	10	34	8	13	5	5	6	9	7
Collar level, above 0.5 mm apron	43	53	39	43	39	44	31	13	16

Radiologist	D			E		F		G	H	
Waist level, below 0.5 mm apron	15	9	5	21	6	12	13	5	5	7
Collar level, above 0.5 mm apron	16	13	15	46	28	38	26	22	35	17

4. Evaluation of Personnel Dose

It is clear that the variable nature of radiation fields in which personnel move in diagnostic radiology and the variable manner in which these fields are monitored can create serious discrepancies between the recorded "skin" dose and the effective skin dose. More importantly, the biologically significant doses may be no more than 10% of the recorded doses. Can reasonable changes be made in the technical approach to personnel monitoring which will render the recorded doses more meaningful?

Since the personnel dosimeter is a sampling device the problem of the "non-typical" reading could be ameliorated by increasing the number of sampling points i.e. by carrying several dosimeters strategically located with respect to critical organs. Since the fields in diagnostic radiology are seldom small, the number of dosimeters need be no more than three or four. This rather clumsy suggestion would not, however, lead to direct estimates of the biologically significant dose.

It would seem that the best solution to the monitoring of biological dose would be a biological dosimeter. The possibilities of such a technology have recently developed through the observation of chromosomal abnormalities in peripheral blood cells following radiation exposure.(29) The incidence and type of such abnormalities appear to be related to the exposure of the subject in a quantitative fashion. The principal disadvantage of this method apart from the dosimetric uncertainties is the cost _per capita_ of such skilled blood examinations. Nevertheless, it is likely that the long-term radiation health of occupationally exposed persons can be followed more meaningfully by such techniques, and on the basis of annual or biannual studies the cost would be little more than that required for conventional monitoring by dosimeters. Perhaps the use of computerized identification methods may bring this method into the justifiable economic range where it could supplement present methods.

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DIAGNOSTIC X-RAY RECORDS-KEEPING

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The question is always, "Records-keeping for what purpose?" Material supplied to me by Conference organizers stated that this Conference is to consider medical radiation information for patients, personnel exposed to radiation while on the job, and the "passerby" who might be exposed to radiation for any reason. So, I repeat, "For what purposes shall the records be kept?" Is the goal to predict certain specific biological effects? Is the goal to supply certain data to the attorney when he goes to court with a case involving radiation exposure? The printed material related to these questions which has accumulated from Hearings, Conferences and Symposia is now extensive and it is not my intention to review it.

From a study of some of the articles, I conclude that there is considerable disagreement about the goals, about what data to collect, and about how the data should be interpreted. In the face of this degree of uncertainty about goals I wish to discuss diagnostic x-ray records-keeping in a decision making context. In this context let us assume that data for a record is to be collected as a basis of decision making for action selection. We assume also that it is useful to collect the data only if some person contemplates taking some action (no action is one of the choices) and he needs the data to decide what to do.

I have introduced the word useful, and it is a key word in the preceding sentence, because a discussion of the usefulness of a data collection system or a diagnostic x-ray records-keeping system leads us to consider the values and costs of the system. Values and costs may be considered either in terms of dollars or in units of utility called utiles.

In my book PRIME[1] I have described a model computer-based medical record system and I have pointed out that a well organized and conscientiously used record system helps the user put his thoughts in order. Any record system has certain dollar costs associated with it. Against these costs must be balanced certain values which are often hard to relate to dollars. Certain types of records are found in diagnostic x-ray departments. The record systems need evaluation in terms of dollar cost versus value to the employee or patient with respect to a definite goal or objective. A list of the types of records should include the following items.

1. Film badge exposure record.

2. Health records of employees.
   A complete blood count at the time of employment and at yearly intervals thereafter is important data to be included in the record.

3. Exposed radiographs of a patient.
   An examination of the exposed radiographs in a patient's film envelope could be made to obtain a rough - a very rough - estimate of radiation exposure. It would be necessary to assume that the radiation field was coned to the size of the radiograph and it would be necessary also to estimate the technical factors of kilovoltage, milliampere-seconds, and filtration. These data should be converted to an estimated absorbed dose to the body and more specifically to absorbed dose in an organ system such as bone marrow.

4. Radiographic consultation reports.
   The patient record contains the radiologist's report of the patient's radiographic and fluoroscopic procedures. This information also might be used as a very, very rough estimate of patient radiation exposure if data on kilovoltage, milliampere-seconds, filtration and number of films are listed. However, other factors must be considered such as the time interval between radiographic examinations. A yearly gastrointestinal examination would require a different weighting factor in terms of radiation effect to the body than would repeated G.I. examinations performed at monthly intervals to follow the course of a healing gastric ulcer.

For females of childbearing age the time of the radiographic examination with respect to the menstrual cycle would also have to be considered. Statements have been made that females in the childbearing age group should have radiographs only in the 10 day interval following a menstrual period. But for an individual female can you be sure that radiographs are "safe" during this 10 day period, and what if she really needs an intravenous pyelogram because she passes a kidney stone outside this 10 day period?

All of these variables introduce weighting factors which are difficult to assess at the present time. A very large number of calculations could be made by computer but the uncertainty of what the calculation results would mean in terms of absorbed body dose to the individual does raise serious questions about undertaking such a task in terms of costs versus value to the patient.

5. Calibration of radiographic and fluoroscopic equipment. These records show that the x-ray output of radiographic and fluoroscopic equipment has been measured for various combinations of kilovoltage, milliampere-seconds and filtration at a given distance. Such tests demonstrate that the equipment is operating satisfactorily.

6. Radiation protection survey of a department. These records are kept to show that the radiation shielding of equipment and radioactive materials in a department has been tested and found to offer adequate radiation protection for patients, physicians and technologists.

7. Continuous monitoring of environment. This type of monitoring is used infrequently in hospitals. A radiation sensing device such as an ionization chamber might be placed in radiographic rooms but not in the direct x-ray beam, at the radiographic control panel, etc. The readings could be recorded on a continuously moving strip chart and could be used to indicate the environmental radiation level at critical locations within a department.

In my recent book on medical decision making[2] I discuss values, costs and relative utilities. Relative utilities are measurable for an individual, but absolute utilities are not. Each person is free to assign arbitrary utility values, and a utility function is determined as follows. If the decision maker is indifferent between two alternatives, the expected utility of the alternatives is the same. The interested reader should see an article by Swalm[3] in the Harvard Business Review for some experiments on the use of expected values and utility theory by business men.

To keep the patient radiation exposure to a minimum an optimum sequence of radiographic tests could be determined for various combinations of differential diagnoses. This subject needs much research. I have discussed [2] the question of finding an optimum diagnostic test sequence by using an example from the work of Fitzgerald, Overall and Williams[4] on the diagnosis of thyroid disease. These investigations emphasize that "There is an optimum sequence of laboratory tests, varying in cost, complexity and possible hazard to the patient."

I wish now to present an argument about the use of film badges by radiation workers, the record keeping of film badge data, and the use of long term radiation exposure data to decide whether a workman did or did not develop leukemia as a result of exposure to radiation and, further, to use this decision to decide whether he is or is not entitled to compensation.

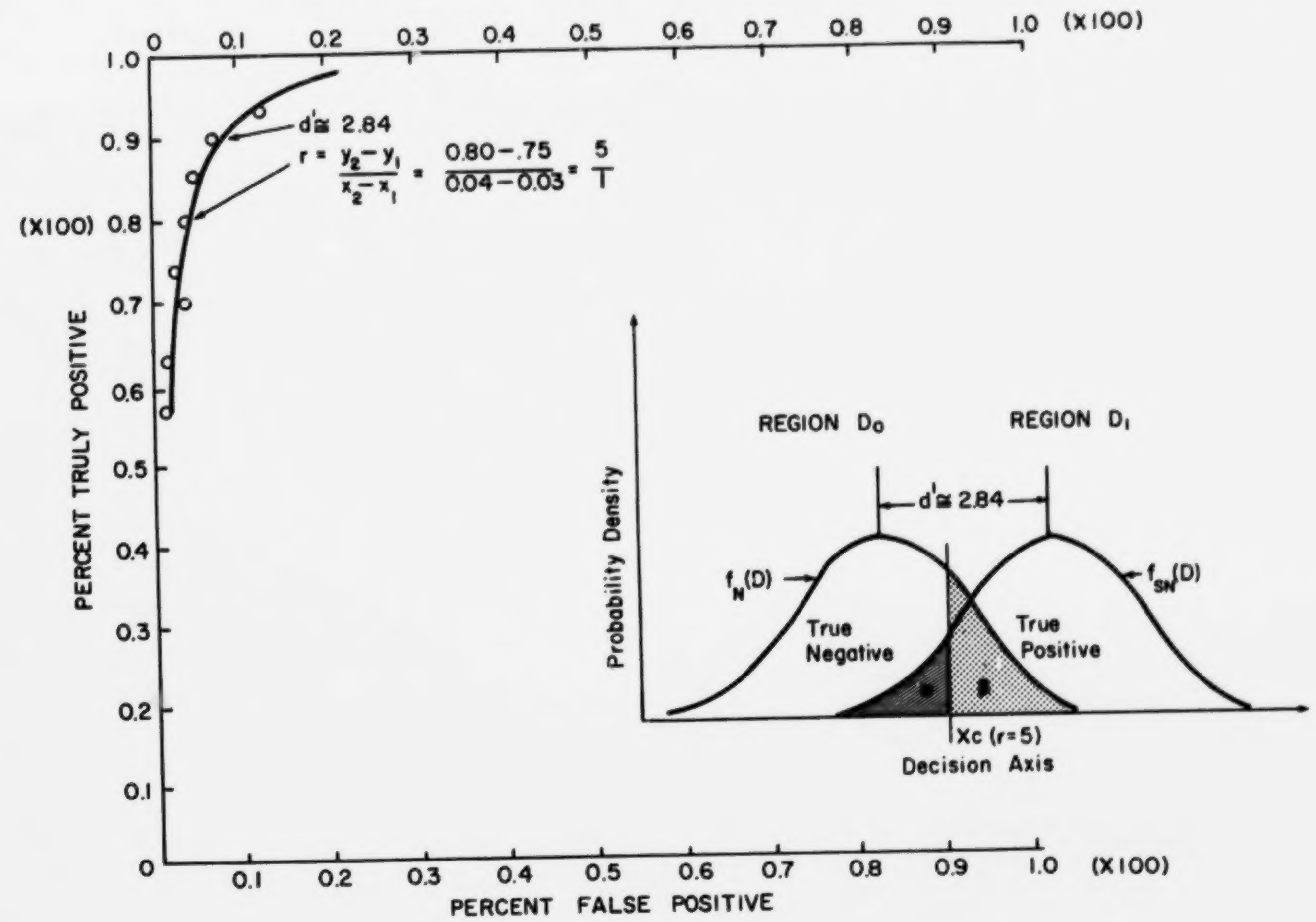
THE CASE OF THE UNCERTAIN CLAIM

The case is that of a 50 year old male who has developed acute myelogenous leukemia. He has worked in the same plant for the past 15 years on projects associated with radiation. He has always been careful to wear his film badge and to wear it in the same place. He has always been in good health, his badge readings have always been below MPD levels, and he has never been in an incident which resulted in heavy exposure. He has asked the plant physician and several consultants, including a radiologists, if his leukemia could be the result of exposure to radiation at work. He has been told "Yes" that leukemia could possibly be a result of his industrial exposure to radiation. Then the man, being a well read fellow, asks the experts "Can you be sure that the leukemia did not come as a result of my radiation exposure?" He receives a different opinion from each expert he consults, indicating various degrees of personal uncertainty as to the probability that his leukemia was caused by radiation. The uncertainty, however, is interpreted by the man to mean that there is a reasonably good probability that his leukemia did result from radiation exposure received on the job. He decides to ask for compensation and files his claim with the Workman's Compensation Board.

The Board is faced with a practical situation of decision making under uncertainty. Let us look at some of the sources of the uncertainty. The accompanying figure shows two population curves marked true negative and true positive. For this argument we agree to call the left hand curve a group (Group 1) of people with leukemia not caused by radiation exposure, and the right hand curve a group (Group 2) with leukemia caused by radiation. A decision is to be made either "Yes, the patient **does** belong to Group 2," or else, "No, the patient does not belong to Group 2."

The second decision implies that he belongs to the first group. We assume only two decisions are possible.

A test or group of tests are used to obtain data which, in turn, are used to separate the two populations. The test applied to each individual is used to decide whether the individual belongs to Group 1 or Group 2. In the figure, d' represents a test or group of tests, and in this case the tests are the man's film badge records extending over a 15 year period. The question now arises, "Is the film badge record acceptable as a test to separate these two populations?" The answer seems to be that it is not. The argument is that the film badge readings should be converted to absorbed dose to the individual, and even then the answer is full of uncertainties if a causal relationship between radiation and leukemia must be established for this man.



If the best available tests fail to supply a satisfactory d' factor, i.e., fail to tell us whether the two populations are well separated or whether they overlap greatly, then the uncertainty about the classification of an individual is very great. Note in the figure that when the population curves overlap, an individual may be classified as belonging to one of four groups. He truly has leukemia (true positive); he truly does not have leukemia (true negative); he is said to have leukemia and he does not have leukemia (false positive, β area); or he is said not to have leukemia and he indeed does have leukemia (false negative, α area).

The false positives and false negatives are errors of the decision making process, and represent actual costs to the system which should be minimized. We have assumed that the man in this case is a true positive but medical diagnosis is a matter of probability. Therefore, there is a probability that the man is a false positive. Since the accuracy of diagnosis of leukemia has not been studied, then the probability of a false positive diagnosis must be considered as another source of uncertainty. When d' is fixed, a reciprocal relationship can be shown between the percent true positive and the percent false positive cases. This is shown in the upper left diagram in the figure. For the decision making situation concerning leukemia, d' is not well understood and it is fair to conclude, therefore, that a relationship between percent true positive and percent false positive cases cannot be demonstrated.

A Workman's Compensation Board confronted with this degree of uncertainty about the interpretation of film badge data would have to decide whether or not the Board should use the data as a guide in its decision that the man's leukemia was or was not caused by radiation. Further, a decision to award or not to award compensation would be based on the same degree of uncertainty of evidence and the Board might wish to find some other acceptable basis for making this decision. What this "some other basis" should be seems to be a matter for the Boards and the Courts to determine until scientific data is available to establish an acceptable d' factor. It seems unlikely that a diagnostic x-ray records-keeping system will be a useful tool in helping to settle this argument in the near future.

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DISCUSSION

DR. BUSHONG: I wonder if we could have Dr. Webster's first slide, the one that had to do with the McMahon study. It's an excellent piece of information. This slide shows the data, I think, from ten different studies having to do with leukemia incidence in children irradiated in utero. In some of the information that I alluded to earlier, showing dose response relationship at the high dose level, we had some reasonable estimate of the dose. When we get to the point where we do not have a precise estimate of the dose, then I think we turn to generating relative values.

Now, it's very interesting when we look at the average risk values. First of all, a risk value of 1.0 means, I believe, that there is no risk, that the risk is that of the general population at large. Now, as we look over the far left-hand column on this slide we see plus or minus figures. A plus or minus two sigma puts us in the 95 per cent confidence level of risk of leukemia. Out of the ten studies, only two of them carry positive value at that point. The second study shows a relative risk value of 1.07. As Dr. Lusted indicated, a value of 1.07 indicates that we might expect seven per cent over the ambient level of leukemia.

In the Stewart study--I would like to ask Dr. McMahon--I don't understand the arrival at the 1.21 relative risk value.

DR. WEBSTER: McMahon's point was that, in his opinion, he had inadequate statistics. Otherwise, you wouldn't get this tremendous level of incidence rate. So, he has weighted the studies according to the volume of material reviewed. And that 1.21 is, therefore, a weighted figure dependent upon the statistics.

DR. BUSHONG: So, it's really tied more closely to the Stewart studies?

DR. WEBSTER: Yes. In this particular case it is the only study which was a very large study.

DR. BUSHONG: But, even in the average values column we have five out of the ten studies that are less than the relative risk of one.

DR. FAYE HEMPHILL: I agree that Dr. Bryan McMahon can do arithmetic and I agree with him on what he has said. But consider the possibility that you are going to initiate a study in this area alone at this point and I say, "Don't do the study. Flip a coin."

DR. WEBSTER: I think it's better than that. The slide shows five less than one and five greater than one in the average column, so I would say it's an honest study. I would say also that there is some information missing from this slide, I think, which has to do with the spread. I think you obviously have to give more emphasis where the standard deviations are smaller.

PATIENT AND PERSONNEL DOSE
DURING RADIOTHERAPY

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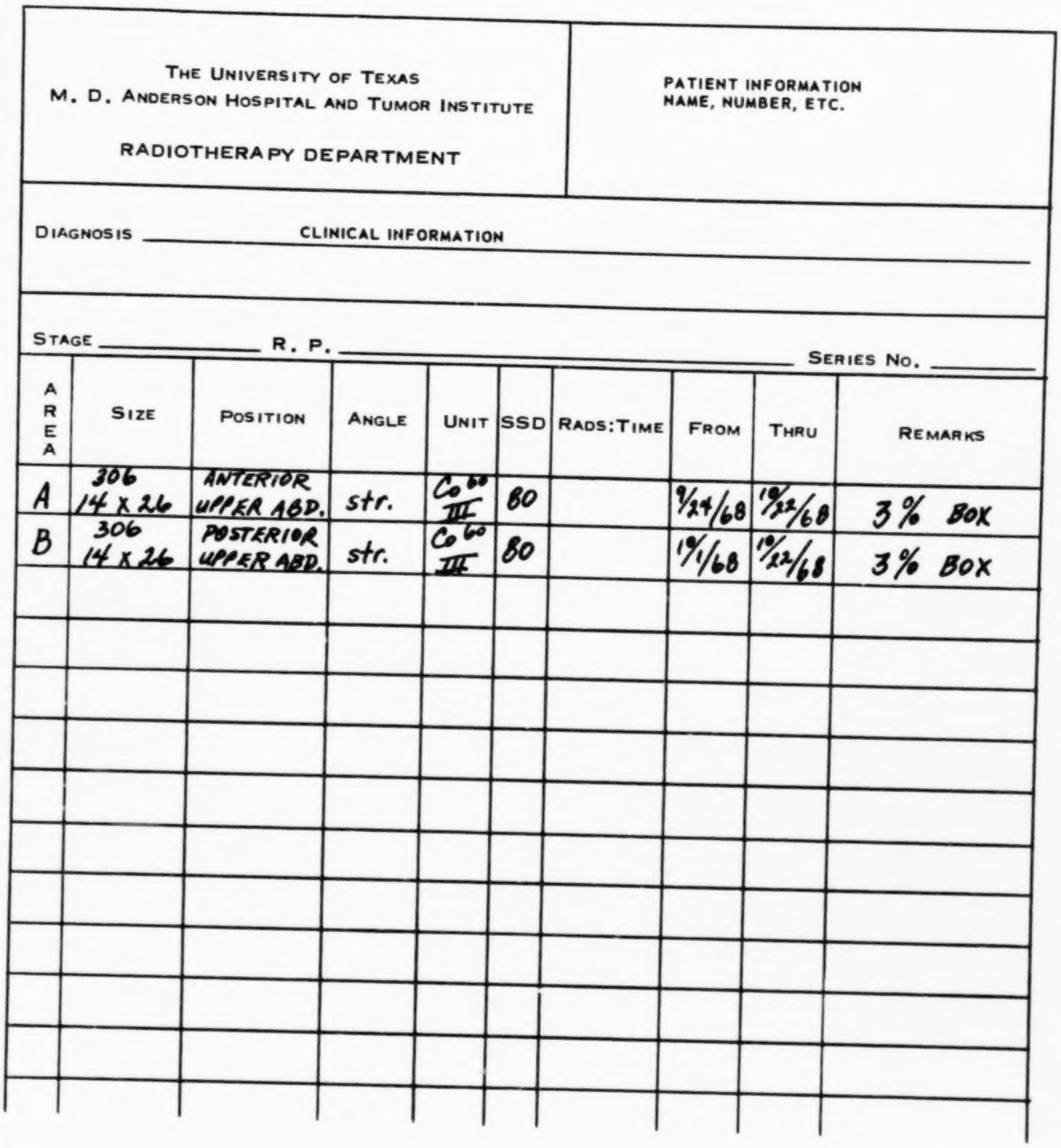
INTRODUCTION

In considering patient and personnel dose during radiotherapy procedures several aspects must be considered. These can be put into several categories: (1) Shielding calculations, installation and protection survey of the therapy machine, (2) Calibration of the machine, (3) Application of the desired treatment, (4) Daily record keeping of dose and treatment, (5) Final check of patient chart, and (6) Filing of records. In order to discuss each of these a sample treatment chart will be investigated to determine the dose to the patient during radiotherapy and finally, the precautions taken to reduce the dose to the operating personnel will be discussed.

PATIENT DOSE DURING RADIOTHERAPY

Figure 1 shows the first page of the patient therapy chart. In the upper right hand corner is space for the pertinent patient information, patient name, number, etc. so that the chart can be identified at a later time. This is followed by space for clinical information and then spaces for information relative to the radiotherapy treatment. In the first column labelled, "area", the treatment fields are listed alphabetically. This is followed by the size of the treatment field, the lower entry is the actual size (in centimeters) and the upper entry is the equivalent field size (in square centimeters) used for calculation purposes and obtained from standard tables. (1) The actual anatomical position of the field on the patient is then listed followed by the angulation of the treatment head necessary to give the treatment. In the column labelled "Unit" the actual machine used to give the treatment is recorded, in this case one of the Cobalt-60 units, and beam quality (H.V.L. or energy) would be listed here for the x-ray machines. Next is shown the source to surface distance (S.S.D.) used during treatment. The following column is blank but can be used for any additional information that may be required. It is generally not used for ^{60}Co treatments but for the x-ray units and betatrons may be used to list information on the calibration. The next two columns indicate the day the treatment started and the day that it ended for a particular field and the last column is for general remarks. Here we see that a blocking box was used and this attenuates the beam by 3%.



THE UNIVERSITY OF TEXAS
M. D. ANDERSON HOSPITAL AND TUMOR INSTITUTE

RADIOTHERAPY DEPARTMENT

PATIENT INFORMATION
NAME, NUMBER, ETC.

DIAGNOSIS ____________ CLINICAL INFORMATION

STAGE ____________ R. P. ____________ SERIES No. ____________

AREA	SIZE	POSITION	ANGLE	UNIT	SSD	RADS:TIME	FROM	THRU	REMARKS
A	306 14 x 26	ANTERIOR UPPER ABD.	str.	Co^{60} III	80		9/24/68	10/22/68	3% BOX
B	306 14 x 26	POSTERIOR UPPER ABD.	str.	Co^{60} III	80		10/1/68	10/22/68	3% BOX

Figure 1. Page 1 of a patient radiotherapy chart containing information relative to the radiotherapy treatment.

Since the dose to the patient will depend on the calibration of the treatment machine considerable consideration should be given to this calibration. For Cobalt-60, since the output decays at a constant rate, the initial calibration must be carried out with great care and thereafter routine measurements are made to ensure that the measured output follows the predicted decayed output. Measurements are made with ionization chambers which have either been calibrated at the National Bureau of Standards (N.B.S.) or have correction factors derived from N.B.S. factors. The history of all ion chambers are kept in a Standard Instruments Data Book so that the correction factors for any chamber at any time can be determined. Calibration of x-ray machines takes place at weekly intervals since the output of these machines may vary with time and if the variations are large, calibrations at intervals of less than a week should be undertaken. All the factors entering into the calibration are recorded in the data books which also contain the initial calibrations and measurements of all factors effecting output such as field size, trimmer position, S.S.D., etc.

These procedures closely follow those given in a statement by the Scientific Committee of the American Association of Physicists in Medicine for the Commission on Radiation Units, Standards and Protection of the American College of Radiology, concerning recommendations regarding calibration of therapy machines.(2) This statement says that the output of treatment machines should be known with reasonable certainty at all times as should the geometry of the beam and its congruence with any localizing device. The statement also recommends the maintenance of log books for each machine. It recommends full calibrations and spot checks at specified intervals for all electrical and radionuclide radiation units and that such units be equipped with a device which continuously monitors the radiation output. It recommends that the full calibration be performed by or under the immediate supervision of a qualified expert such as one certified in radiological physics. Its recommendation for full calibrations and spot checks are as follows:

"I. Full Calibration

In the case of x-ray, gamma-ray and electron beams a full calibration encompasses the determination of the exposure-rate or dose-rate for at least one field size for each radiation quality and for each treatment distance which may be used. Where variation of the field size or change of collimator type may change the exposure-rate by an amount exceeding ± 3 percent, the exposure-rate or dose-rate shall be determined for such fields, unless the amount of change has been previously established. In the case of x-ray beams, the quality of radiation (half-value layer) for each set of operating conditions in use shall also be determined. In the case of electron beams, the electron energies shall be determined A full calibration of apparatus for radiation beam therapy shall be performed:

(a) whenever the radiation monitor or other meter related to the radiation output shows a continued, significance change in its normal reading'

(b) immediately following major mechanical or electrical alterations of the radiation source, its housing, power supply or controls, or following replacement of the radiation source;

(c) at intervals not exceeding one year.

II. Weekly Spot Checks

A spot check at weekly intervals during periods when the machine is in use is recommended for those parameters which may change suddenly without giving an external indication of change including:

(a) the exposure-rate or dose-rate or a quantity related in a known manner to these entities for one typical set of operating conditions for units which do not have a beam monitoring device;

(b) the uniformity of the beam for units in which the uniformity of the beam is critically dependent upon the electrical or mechanical alignment of the unit, such as units utilizing a flattening filter for x-ray beams;

(c) the energy of the electrons, for an electron beam unit.

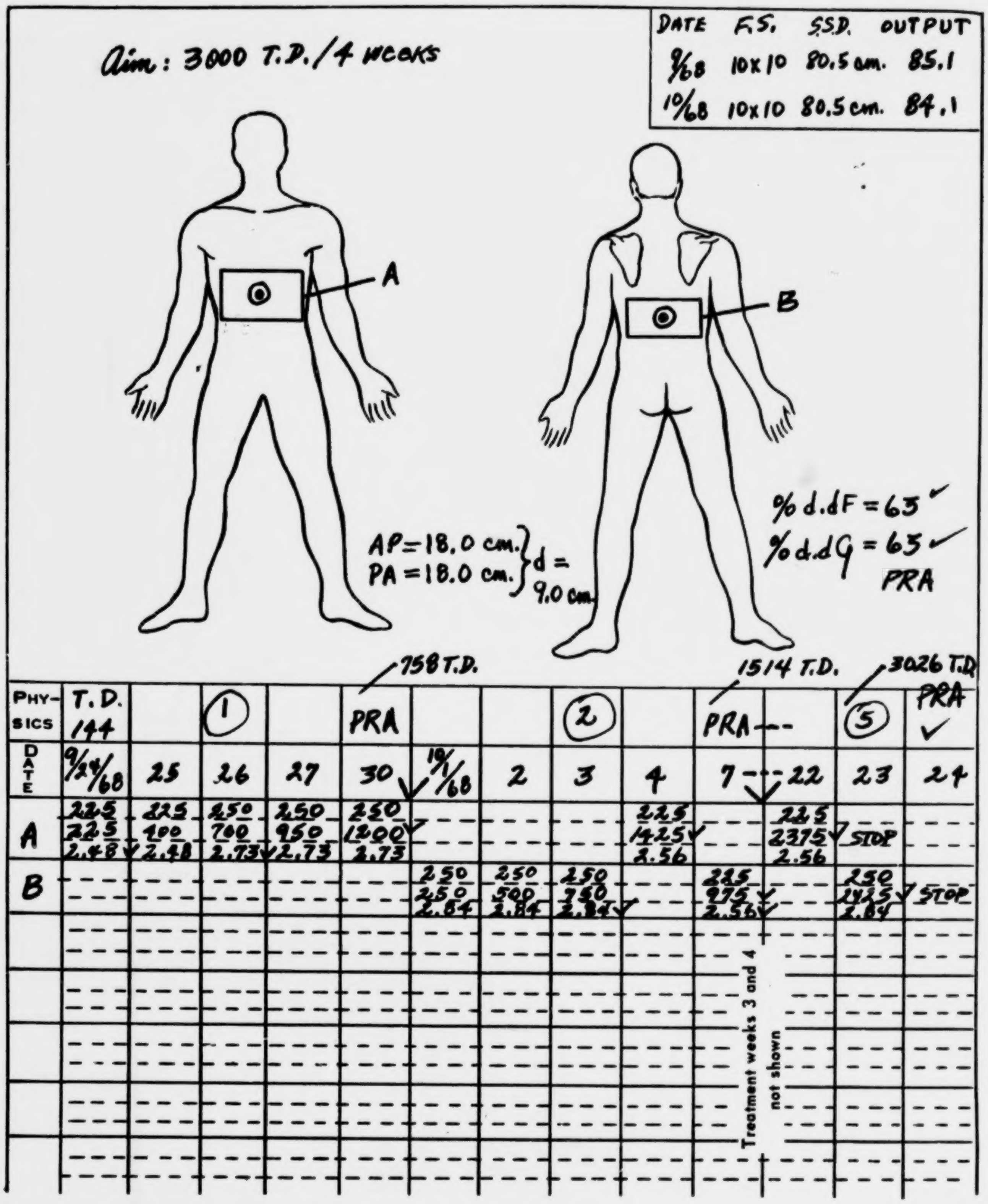
III. Monthly Spot Check

A monthly spot check is recommended for those parameters which are likely to change only a small amount or those whose change modifies the treatment in a minor way, including:

(a) determination of the congruence or otherwise between the radiation field and the field indicated by a localizing device;

(b) determination of the exposure-rate or dose-rate or a quantity related in a known manner to these entities for one typical set of operating conditions, for units which have beam monitoring devices."

Page 2 shown in Figure 2 is the actual work sheet and daily record of the treatments. In the upper right hand corner, the standard output of the treatment machine is recorded. Since this is a Cobalt-60 treatment the output will be adjusted each month to allow for the decay of the cobalt and if the treatment lasts over two separate months, both outputs are recorded. The date, field size (F.S.) and S.S.D. of the standard calibration is shown along with the output in rads/min. This output is obtained from the routine calibration of the treatment machine which is entered in the data book kept for each machine.



Aim: 3000 T.D./4 weeks

DATE	F.S.	S.S.D.	OUTPUT
9/68	10x10	80.5 cm.	85.1
10/68	10x10	80.5 cm.	84.1

AP = 18.0 cm.
PA = 18.0 cm.
d = 9.0 cm.

% d.dF = 63 ✓
% d.dG = 63 ✓
PRA

758 T.D.
1514 T.D.
3026 T.D

PHYSICS	T.D. 144		①		PRA			②		PRA---		⑤	PRA ✓
DATE	9/24/68	25	26	27	30	10/1/68	2	3	4	7	22	23	24
A	225 225 2.48 ✓	225 450 2.48	250 700 2.73 ✓	250 950 2.73	250 1200 ✓ 2.73	---	---	---	225 1425 ✓ 2.56	---	225 2375 ✓ 2.56	STOP	---
B	---	---	---	---	---	250 250 2.84	250 500 2.84	250 750 2.84 ✓	---	225 975 ✓ 2.56 ✓	---	250 1425 ✓ 2.84	STOP
	---	---	---	---	---	---	---	---	---	---	---	---	---
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Treatment weeks 3 and 4 not shown

Figure 2. Page 2 of a patient radiotherapy chart containing calculations and daily record of treatment. Note that the output in the upper right hand corner is in units of rads/min.

Below the output on page 2 an outline of the patient is stamped upon which is marked the treatment fields listed on page 1. In the upper left hand corner of page 2 the physician has indicated the air of the treatment, in this case 3000 rads tumor dose (T.D.) in 4 weeks. Since there are 5 treatment days per week this results in approximately 150 rads T.D. per day. Also on this sheet is recorded the measured diameters of the patient and the depth at which the tumor dose is to be calculated. As this is a parallel opposed treatment the dose at the mid-point of the patient is required. From standard depth-dose tables (3) for the treatment distance and area under consideration the percent depth dose at the depth of interest is found and recorded. In this example the average diameter was 18.0 cm and the depth of interest was 9 cm and the percent depth dose was 63% at this depth for 80 cm S.S.D. and the field sizes under consideration. The given dose (G.D.), which is the 100% dose for a given field received by the patient is obtained by dividing the tumor dose by the percent depth-dose. In this example the daily given dose was approximately 230 rads. Since the calibration is in terms of the maximum or given dose the time required to administer the given dose must be calculated. The output of the machine depends on S.S.D. and also treatment area and the dependence of output on these parameters for the particular machine under consideration is determined during its initial calibration. This information is then incorporated in a dose-time calculator in which the treatment distance can be set opposite the treatment area and the time required for any dose read off a circular slide rate. These calculators can be set each month to allow for decay.

On page 2, therefore, the following rows are used. Row 1 marked, "Physics" is used for various notations, Row 2 marked "Date" indicates the day on which the treatment was given and the remaining rows list the treatment fields, alphabetically again. The top subrow shows the daily given dose, the middle subrow gives the accumulated given dose and the bottom subrow gives the time required to deliver the daily given dose. For machines where output varies with time and the dose is described in monitor divisions, the number of divisions would appear here. Also, account is taken of such things at attenuation through blocking trays, in determining this time. In the row marked physics the treatment weeks are listed and at the end of each week the accumulated tumor dose is calculated and entered. The chart is also checked weekly for any errors in arithmetic, depth-dose data, etc., and if correct, it is initialled. Any errors found are brought to the attention of the physicists and physician for correction. At the end of treatment, the completed chart is again checked by the physicist before it is sent to storage. At present all charts are kept indefinitely and some now go back twenty years.

It should be pointed out here that the form of the chart is not as important as the information contained on it. Each institution has different forms but they all contain essentially the same information so that the dose delivered to the patient each day can be checked. In fact, the form will change from time to time to better display and convey the information.

Although every effort is made to ensure that the calculations are correct, it is still required that the patient be set up and the treatment administered correctly. Some institutions may place a recorder on the timer of their Cobalt-60 unit so that a permanent record of the time the machine was on is obtained. Another approach being developed for Cobalt-60 machines is to have the machines automated so that the time of treatment, and maybe other parameters, would be controlled by a card which would remain with the patient chart. This is also a definite possibility with the high energy treatment machines since the number of parameters that have to be set on these machines can be fairly numerous. For example, with high energy betatrons or linear accelerators that can be used for either x-ray or electron beam treatment these parameters could include modality, energy, filter, field size, distance, angle and dose setting. In order to make sure that the settings are correct and that no more than the prescribed dose is given semi-automatic systems and back up devices must be used. This becomes especially important for linear accelerators where the dose rates for the electron beams can be quite large. Card reading systems are being developed so that machines will not come on unless the correct parameters are set and the card can be kept with the patient chart.

PERSONNEL DOSE DURING RADIOTHERAPY

With adequate design of the equipment and shielding of the treatment room the exposure received by the operators can be kept well below the maximum permissable levels. The treatment room should be so designed and the shielding thick enough to reduce the radiation to safe levels. When a machine is installed a protection survey should be made to determine the adequacy of the shielding. If weak spots are found in the shielding or that certain orientations of the machine increase the exposure level outside the treatment room additional shielding should be added or the movement of the machine limited. The results of the survey along with indications of any modifications should be entered into the machine data book as a permanent record. The treatment rooms will also have safety interlocks on the doors, warning lights, and room monitors. All of these precautions are required by state regulations. These devices should be checked at regular intervals and a notation entered into the data book that they are functioning correctly.

All personnel working in the area are required to wear film badge monitors which are processed once a month. These records are stored and at any time the total dose received by any of the personnel can be found. The average exposure measured by these film badges is of the order of 30-50 mR/month for the nurse technicians who set-up the patients and run the machines. As an extra precaution pocket ionization dosimeters are worn. In the event of a suspected accident (for example the source drawer of a Cobalt-60 machine may become stuck partically closed) these dosimeters can be read immediately and although they are not accurate they will indicate whether an accident has occurred and give an indication of the dose received. Emergency procedures are also posted by each machine so that in the event the source will not turn off the patient can be removed as quickly as possible and the machine shut off manually with a minimum of exposure to the operator.

Although this discussion has been limited to external beam radiotherapy the same type of precautions and procedures are taken for intracavitary and interstitial radiation treatment with radium, ceasium, gold, iridium, etc. Special attention should be given to radium because of the possibility of leaking radium sources and these should be checked at regular intervals. These cases also present a special hazard to the nursing personnel and devices are being developed for intracavitary treatment that will allow the sources to be automatically removed from the patient and placed in a safe while the nursing personnel tend to the patient. Also when these devices are being unloaded, care should be taken that all the sources are accounted for and the patient and room should be monitored after treatment to make sure that no sources are left around.

CONCLUSION

In conclusion, it can be stated that the patient dose will be determined by (1) machine calibration and machine parameters which should be determined at installation and routinely checked; (2) by patient parameters and the clinical aim and (3) by correct calculation of treatment time and administration of the treatment. All the pertinent information should be included in the data book and on the patient chart so that the total dose and the daily given doses can be confirmed.

Personnel dose will be determined by (1) adequate shielding and protection of the machine; (2) safe procedures that result in minimum exposure to the personnel. Records should be kept of a protection survey and the operation of safety devices on the machine, records must also be kept of the exposures measured by film badge monitors.

It must, of course, be realized that accidents and errors will occur. The procedures described here have been developed over the years in order to reduce these to a minimum and when they do occur, to be able to detect them quickly enough so that corrective action may be taken.

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RECORDS-KEEPING IN A RADIOTHERAPY CENTER

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Among all the circumstances where individuals are exposed to radiation the area of radiotherapy is unique in that the exposure to radiation is intentional, planned, and controlled rather than unsuspected, incidental, or accidental. Therefore, we may look to the radiotherapy record as a model of information to appraise the radiation exposure and the effects.

The focus of this conference is on medical information for litigation and we may consider first the circumstances under which litigation may arise. The common ground of malpractice actions generally, is dissatisfaction with the result of treatment. Whether or not this dissatisfaction is reasonable and justifies compensation, is to be settled to the satisfaction of one party compensation, is to be settled to the satisfaction of one party by the process of litigation. A brief outline of the manner in which an alleged radiation injury might occur, will serve to indicate the kinds of information necessary to arrive at a reasoned decision.

The danger is a high dose effect whereby tissues exposed to radiation are so damaged that the resulting injury is unacceptable for the benefit received. It could arise in several ways.

1. It may be an intended result. In the therapist's judgment the damage caused by a very high dose of radiation may be a necessary and justifiable side effect to eradicate cancer.

2. It may be an unintended result. Accident or error on the part of technician or physician may occur in the course of planning or delivering treatment.

3. It may be unintended and unforeseen. There are individuals with an unpredictable sensitivity to radiation. Exaggerated sensitivity to radiation may occur due to an unsuspected process, e.g. inflammation or infection in the treated area that could augment the reaction beyond the limits of recovery.

4. The advancing disease may be undeterred by the treatment offered and progressing to ulceration, necrosis, perforation or pain, the unhappy sequence may be ascribed to the radiation.

5. The result may be unwanted by the patient, even if the treatment was successful as planned. Sterility may be an inevitable

result of irradiating a pelvic lymphoma, but if the patient was not informed her consent would be invalid and even successful treatment would not protect the physician from a charge of battery or negligence.

These possibilities are not inclusive of events that lead to medical or legal injury, but they demonstrate that in relating radiation and effect the recording of dose as a single number is totally inadequate information for a reasoned decision as to causation and liability.

When radiation is used for treatment, information in the record is inclusive to a degree that would be impractical in documenting diagnostic or occupational exposures. Nevertheless a thorough understanding of the available information in the radiotherapy record serves to demonstrate the nature of dose and the meaning that the term acquires when backed by enough information. The radiotherapy record contains information of several different types, all of which contribute importantly to establishing the relation between the radiation given and the effect produced.

1. History and examination: This portion of the record documents the information on which the radiotherapist based his recommendation and decision as to treatment. This is diagnosis in the broadest sense. Diagnosis is more than a polysyllabic name for classification and cross-filing; the literal meaning is "to know through and through". It includes the development of the condition, any previous treatment, any concurrent disease, the probable course of the disease if untreated and the anticipated course if treatment is offered. Pertinent laboratory work, pathology and x-ray reports, operative notes and clinical examinations are documented. Erroneous or absent pathology and x-ray reports have resulted in inappropriate treatment and litigation. Foreseeable hazards due to treatment, the disease itself, or of the two combined should be noted.

2. Consent to treatment: Much of medical practice has been regarded in common law as a form of battery excused only by the patient's consent. This includes not only surgery, but any touching of the patient and clearly any administration of radiation for diagnosis or treatment. Consent may be implied from the patient's submission, it may be explicit and today it should be informed. This is not the place for detailed discussion but the record should contain evidence of a consent that is valid in the light of current legal decisions.

3. The treatment plan: This is a blueprint of the treatment planned and given, that documents the distribution of radiation

within the individual in a comprehensive fashion. This could not result from the prescription of dose as a single numerical value. Some such internal distribution of radiation occurs whenever an individual is exposed to radiation- diagnostic, occupational or accidental. Such distribution could not be reconstructed from a film badge reading and conclusions as to dose and effect would be tenuous and speculative to a degree that would be completely unacceptable if a patient's welfare were involved.

The treatment plan for delivering radiation may be augmented by the use of a variety of devices- molds, casts, stents, and applicators designed to control the delivery of radiation and in so doing they contribute solid information to the record of what treatment was given and how it was carried out. Today computer technics contribute heavily to treatment planning by virtue of the detail that can be added to the description of dose by tireless computation.

4. Localization and verification films: The location of the tumor to be treated and of tissue to be protected, of size of beam, its angle and site of entry and exit, can be found by use of diagnostic x-ray equipment to simulate the actual treatment. These same essentials can be confirmed using the treating beam. Localization films and verification films constitute convincing information as to what was exposed to radiation.

5. The treatment record: The day-by-day recording of the measured amount of radiation delivered and dose accumulated is the most conspicuous element of information that the radiotherapy chart may contain. There is rather wide latitude in how this record is constructed but it is primarily numerical in content. Each example represents an attempt to produce a clear, complete and accurate account of the patient's progress through the course of treatment. It is a bookkeeping chore and vulnerable to human fallibilities with numbers. It is a part of the record and a source of information to be studied with care as to arithmetic and caution as to interpretation. Even if the arithmetic is correct it may not be right to assume that equal numbers represent equal doses, equally safe or equally dangerous. The modifying factors are time and volume and geometry, biology and pathophysiology, that under the most carefully controlled circumstances require value judgments and under chance conditions of exposure make numerical accumulations an exercise in arithmetic of only remote relation to the problem of cause and effect of radiation injury.

6. Progress notes: As the treatment record is an account of

the physical aspect of dose, so the progress notes of tumor response and patient reaction represent a running account of the biologic component of dose. Often surprising and sometimes inexplicable variance occurs between the radiation delivered and the response that results. The clinical appraisal of the response is an essential confirmation or correction of the dose as predicted by the prescribed amount of radiation in physical units. This is information as to dose that is not subject to dispute even if in conflict with physical measurement or calculation.

7. The illustrations: A pictoral record, whether sketch, anatomic stamp, photograph or radiograph, makes a contribution to documentation that goes beyond reliance on description or recall. Serial examinations are necessary to provide information on radiation reaction or response and photographic records allow convincing comparisons.

This is the information available, or that could be available, on the use of radiation for treating a patient. This information is capable of meeting the legal definition of "PROOF: The conviction or persuasion of the mind of a judge or jury, by the exhibition of evidence, of the reality of a fact alleged".

While the radiotherapy center is engaged in carefully planned exposure of patients in the course of treating disease, the presence of radiation creates a potential hazard as in any other branch of radiation industry with certain differences as to the who and why and how and when. There are four classes of individuals potentially exposed to unwanted radiation.

1. For personnel actually engaged in the treatment activities, the procedures and hazards do not vary greatly from any other occupational exposure. The individuals are specially trained; they have at least basic information as to radiation hazards and protection; they are in a controlled environment; they are available for continuing health surveillance; they continue in their chose occupation voluntarily.

2. Non-radiologic personnel are also subject to occupational exposure in the operating room or in the wards or rooms where patients may be receiving irradiation as from intracavitary radium, interstitial sources or internally administered radioisotopes. Physicians, nurses, and supporting personnel are apt to be woefully uninformed or misinformed concerning radiation. Real or imagined exposures are equally disturbing to the many young women in these positions who are contemplating pregnancy. Shallow draughts of protection intoxicate the imagination but deeper instruction may produce a

sober peace of mind.

3. Family and friends of patients carrying an internal source of radiation are subject to exposure. There is little or no opportunity for instruction but a standard protection procedure is needed.

4. Strangers to patient and physician fall within Murphy's Law - no matter how carefully one may plan to control the radiation the possibility of exposure to an individual, unknown and uninvited to the scene, will become an actuality.

For all but the patient, who may be exposed as a result of operation of a radiotherapy center, the chief reliance is likely to be the familiar film badge. The principal advantage of the film badge is that provision of badges to all concerned is evidence of care; being careful may not prevent an accident, and it may not prevent litigation, but it does make a very good defense.

The documentation of what is irradiated, of the amount and distribution of radiation given, and of the effect achieved, is a meaningful statement of dose. We are unwilling to settle for less, when successful treatment hinges on predicting a precise relationship between the radiation prescribed and delivered, and the effect produced- both immediate and remote. Specifically we would be unwilling to pin hopes of cure, prognosis of injury or evaluation of prior treatment, on the reading of a film badge if this were the available information on what radiation was delivered, where it was delivered or how it was delivered. The reliance gap is clear in the matter of treatment. It is no less real if the matter is occupational exposure. The film badge is good for something. It does not yield the wearer's dose. It reveals only that the film badge, perhaps (but not assuredly) carried by the wearer on his rounds, appointed or unappointed but uncharted, encountered a radiation environment that in instant exposure, or by increments, or by slow and constant accumulation, reacted to the final level of exposure. This odyssey is then described in the solid simplicity of the film badge reading "Current monthly exposure in Rems,- .043".

The film badge has a useful function. It s blackening beyond the permissible level documents a break in protection. If the useful information is caught when it happens, or within a period of time while reconstruction is still possible, the break can be detected and corrected thus preventing further exposure. It is a monitor of the environment and in this role it is a valued tool. It can perform this service for radiologic personnel, for non-radiologic personnel and for identified contacts of patients carrying radiation. It cannot of course cover the unidentified contact.

The purpose of environmental monitoring would be more efficiently carried out by fixed detectors capable of instant and continuous reading. Any break in protection would be detected certainly and swiftly. If this were matched with the badge reading of the individual exposed individuals would be identified and the time and magnitude of exposure established.

SUMMARY

Record keeping in a radiotherapy department comprehensively documents the administration of radiation and the effect produced.

This is the application of the concept of dose, that if the administration of the agent is carefully planned, and meticulously executed, then a desired effect previously demonstrated can be predicted and duplicated.

To the degree that radiation is less certainly controlled, that the timing and distribution are unknown, and that the effect is not specific or could have resulted from other causes, the relationship between cause and effect dissolved and dose is not an applicable term.

PATIENT AND PERSONNEL DOSE DURING RADIOISOTOPE PROCEDURES

James Kereiakes, Ph.D., Harry Horwitz, M.D., and Eugene L. Saenger, M.D.,
Radioisotope Laboratory, General Hospital, Cincinnati, Ohio and Henry
Wellman, M.D. and Vince Sodd, Ph.D., Nuclear Medicine Laboratory,
Bureau of Radiological Health, Cincinnati, Ohio

Nuclear Medicine is becoming a significant source of population exposure to ionizing radiation. The phenomenal growth of this medical specialty, probably the most rapidly growing specialty in the United States today, hinges on several interrelated factors. First of all, the realization of the usefulness of radionuclides for medical diagnosis is just becoming apparent to the medical community. Second, technological advances in radiation detection and imaging instrumentation as well as radiopharmaceutical development have tremendously expanded these potential beneficial applications. Procedures in most laboratories doubled in the period between 1958 and 1965, a growth rate of about 15 percent per year. These figures are borne out in the recent National Center for Radiological Health report "Survey of the Use of Radionuclides in Medicine: Preliminary Report" (1). In addition, it has been our experience at the Radioisotope Laboratory at General Hospital, Cincinnati, Ohio, that between 1965 and 1968 there has been an additional doubling of procedures, a growth rate of 33 percent per year. Since approximately 95 percent of the procedures in Nuclear Medicine are diagnostic in nature, it is probably best compared to diagnostic radiology. We are, however, in a unique position with Nuclear Medicine not possible in the early days of radiology; that is, we are in a position prospectively to influence dose reduction procedures and concepts in this field. Furthermore, the growing field has been commendably "dose conscious," and higher dose procedures have been replaced and abandoned as soon as new techniques are available, usually with the premise that minimal doses necessary to obtain valid information be used.

This presentation will review personnel and patient doses as a result of radioisotope procedures, beginning with some typical personnel exposures in our laboratory. These data are based on commercially supplied film badges worn at the waist level by three full-time technicians (in a radioisotope laboratory that averages 250 procedures per month, two-thirds of which involve scanning procedures). The average exposure for the 1965-1966 period was 36 mR for each three-month period, with a range of 11 to 63 mR. The average exposure for the 1967-1968 period was 110 mR per three-month period, with a range of 33 to 215 mR. These data indicate a three-fold increase in exposure, because of the increased number of procedures in the 1967-1968 period, as well as the initiation of the use of generators in January 1967. However, even the 1967-1968 figures do not approach the maximum permissible occupational exposure of 100 mR per week (or 1200 mR for 3 months) recommended in the National Commission on Radiation Protection Report No. 33.

One of the difficulties encountered with personnel exposure, particularly with the initiation of the use of generators, is dose to body portions other than what is considered to be whole body, namely to extremities. An example of such doses is presented by one of our technicians involved in eluting ^{99m}Technetium from a ^{99}Molybdenum generator. The technician wore six film badges, which indicated the following doses in one week: Neck-13 mR; waist-27 mR; right wrist-33 mR; left wrist-31 mR; finger of right hand-112 mR; finger of left hand-101 mR. These data are an average of two separate one-week work periods involving clinical procedures with patients and involving six elution procedures in which a total activity of 900 millicuries of Technetium -99m was milked per one-week work period. Recommended permissible exposure levels to extremities are given as about 15 times maximum permissible exposure levels to whole body, or about 1500 mR per week. In order to minimize personnel exposure, technicians are rotated so that each technician is involved in elution procedures only approximately 1/3 of his work time. Readings of film badges worn by personnel are maintained in a permanent file.

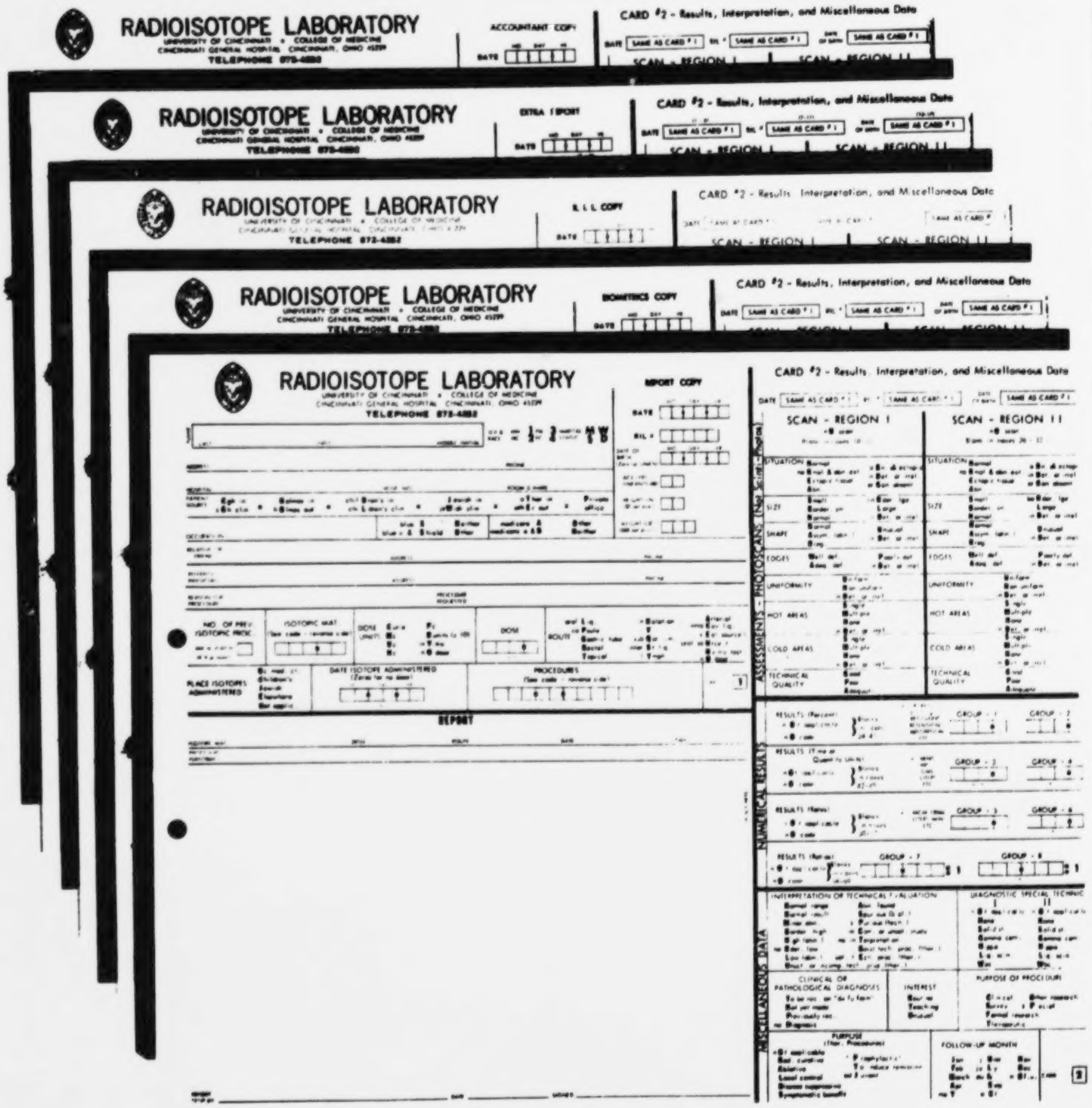
There appears to be general agreement that both professional and technical personnel are receiving an increasing but not excessive exposure and that this is probably due to the increased number of clinical procedures as well as the increasing number of high activity generators in most laboratories. Perhaps results are related to the fact that through the years two systems of radiation safety procedures have been developed, one for the therapeutic use of radioisotopes and the other for diagnostic procedures. In the past, diagnostic procedures have always been at low activity levels, i.e., a few microcuries. Now, suddenly, diagnostic activity levels are millicurie amounts, and handling procedures have perhaps not been adjusted accordingly. Further decrease in personnel exposure can perhaps be achieved by re-education concerning radiation safety procedures.

With the increased use of radionuclides and the advent of radionuclide generator systems, new problems in nuclear medicine personnel protection have been created. Reports of both facility contamination and internal contamination of personnel are increasing. Consequently, the use of film badges alone for personnel monitoring is not adequate; additional detection systems for recognizing exposures are desirable. Periodic in vivo or bioassay monitoring of personnel is recommended to assess possible internal contamination levels. Use of a whole body counter is desirable for this purpose. In our laboratory, personnel are counted periodically (at least once every six months) in a whole body counter. The whole body counting procedures have resulted in the detection of picocurie levels of I-131 in one professional employee and picocurie levels of Technetium-99m and Iodine-131 in one technician. These data are recorded on a regular radioisotope laboratory patient chart for each worker. We will refer to this chart in more detail in a few minutes. Each worker then has a radioisotope laboratory patient number and the results of his repeated whole body counting procedures are entered as a permanent record on his chart.

Next we will discuss patient dose as a result of radioisotope procedures. When each patient is sent to the Radioisotope Laboratory for a clinical procedure, a form of the type shown in figure 1 is filled out. This form is coded for computer processing. It consists of five sections: patient information; clinical report; results; interpretation; and miscellaneous data. Of particular importance in this presentation are the information blocks at the bottom of the patient information section (see figure 2). These include: number of previous isotopic procedures; isotopic material; dose (which should really be the administered activity); route of administration; date the isotope was administered; and clinical procedure. The back of the form contains certain codes which can be used for supplying information to the isotope material block and to the procedures block. As I indicated previously, a chart of this type is also maintained for each worker in the laboratory for monitoring purposes. There are five color-coded copies of this form, distributed as follows: referring physician; biometrics; radioisotope laboratory patient chart; accountant; and an extra copy.

The increasing use of radionuclides in medical diagnosis and research requires that we have greater knowledge of radiation exposure to patients than these forms provide. Since 1964, concentrated efforts have been made by several groups throughout the United States to obtain the information required to better estimate patient doses. In October of 1964, the Society of Nuclear Medicine initiated a Medical Internal Radiation Dose (MIRD) Ad Hoc Committee to serve the needs of nuclear medicine in the determination of radiation dose to patients who are administered radiopharmaceuticals. Tissue distribution data relating to biologically-distributed radionuclides had been gathered primarily for the purpose of establishing Health Safety Standards for workers exposed to elemental forms of radionuclides rather than specific chemical forms (radiopharmaceuticals). Thus, it was generally agreed that the data and information available to the profession at that time were not adequate to determine to the desired accuracy the dose resulting from the use of radioactive materials in diagnostic studies. The needed data were scattered and not easily available. Also, there was doubt that the data were the best that could be generated, in view of new developments in nuclear spectrometry, computerized dose computation techniques and improved measuring techniques for determining the tissue distribution and life-times of radiopharmaceuticals in patients. Finally, the increase in the use of radionuclides that emit low-energy photons presented some serious challenges to the accepted methods of calculating dose.

The data which we will present today include the efforts of the following: the MIRD Committee (2); the Radioisotope Laboratory (headed by Dr. Eugene L. Saenger) of the University of Cincinnati College of Medicine; the Cincinnati Nuclear Medicine Laboratory (headed by Dr. Henry Wellman) of the Bureau of Radiological Health; and Dr. Edward Smith, Jackson Memorial Hospital, Miami, Florida. The average dose from an internally administered radionuclide varies with the radionuclide, its chemical form and its route of administration.



ACCOUNTANT COPY

EXTRA REPORT

R.I.L. COPY

BIOMETRICS COPY

REPORT COPY

RADIOISOTOPE LABORATORY
UNIVERSITY OF CINCINNATI • COLLEGE OF MEDICINE
CINCINNATI GENERAL HOSPITAL CINCINNATI, OHIO 45229
TELEPHONE 872-4282

DATE

NO. OF PREV ISOTOPIC PROC

ISOTOPIC MAT

DOSE

ROUTE

PLACE ISOTOPES ADMINISTERED

DATE ISOTOPE ADMINISTERED (Zeros for no dose)

PROCEDURES

REPORT

CARD #2 - Results, Interpretation, and Miscellaneous Data

DATE SAME AS CARD #1

SCAN - REGION I	SCAN - REGION II

SITUATION

SIZE

SHAPE

EDGES

UNIFORMITY

HOT AREAS

COLD AREAS

TECHNICAL QUALITY

ASSESSMENTS - PHOTOSCANS

RESULTS

GROUP - 1

GROUP - 2

GROUP - 3

GROUP - 4

GROUP - 5

GROUP - 6

GROUP - 7

GROUP - 8

NUMERICAL RESULTS

INTERPRETATION OF TECHNICAL EVALUATION

DIAGNOSTIC SPECIAL TECHNIC

CLINICAL OR PATHOLOGICAL DIAGNOSES

INTEREST

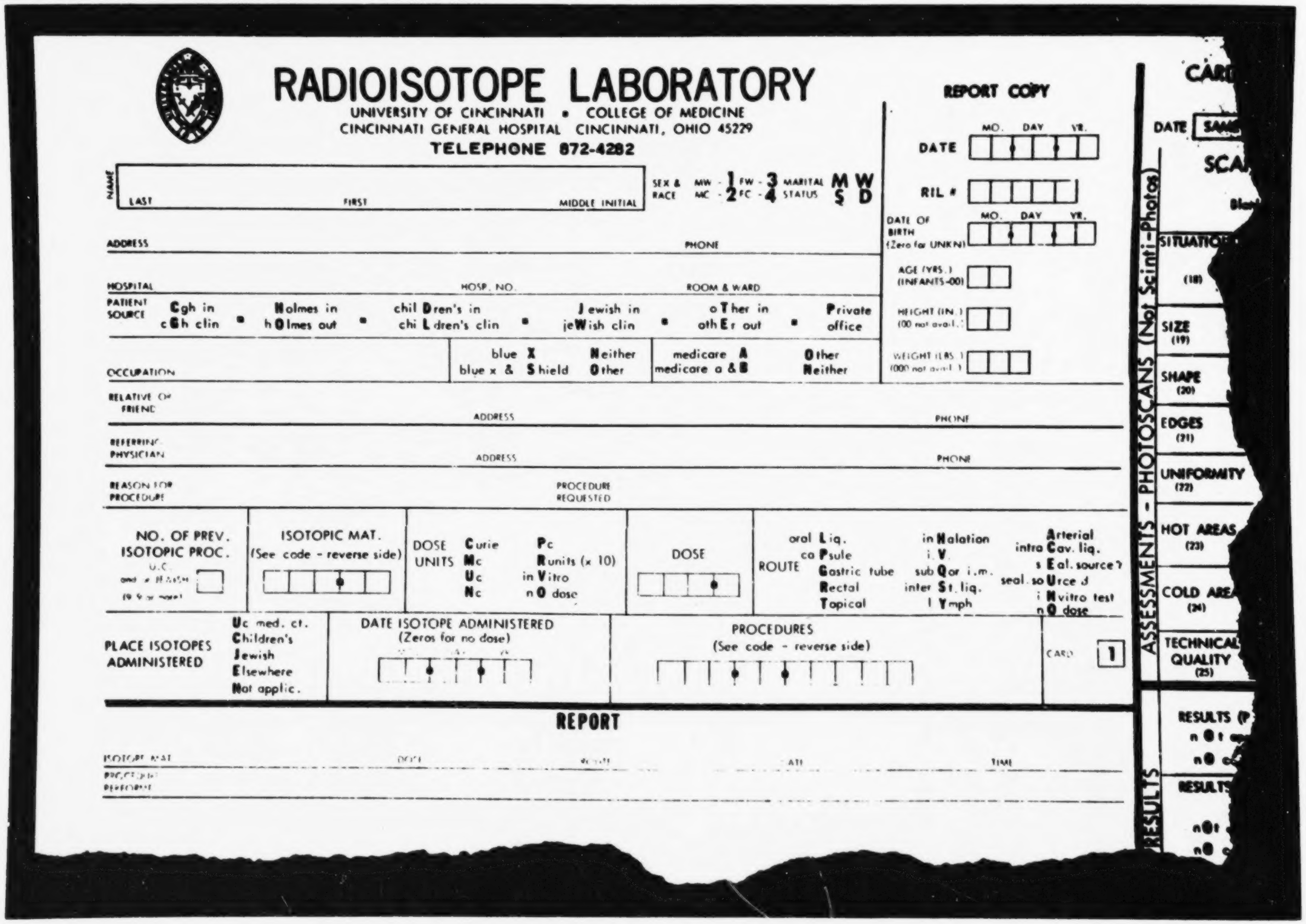
PURPOSE OF PROCEDURE

PURPOSE

FOLLOW-UP MONTH

MISCELLANEOUS DATA

Fig. 1. Radioisotope laboratory patient form



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REPORT COPY

DATE MO. DAY YR. ☐☐☐☐☐☐
RIL # ☐☐☐☐☐
DATE OF BIRTH (Zero for UNKN) MO. DAY YR. ☐☐☐☐☐☐
AGE (YRS.) (INFANTS-00) ☐☐
HEIGHT (IN.) (00 not avail.) ☐☐
WEIGHT (LBS.) (000 not avail.) ☐☐☐

NAME LAST FIRST MIDDLE INITIAL
SEX & RACE MW - **1** MC - **2** FW - **3** FC - **4**
MARITAL STATUS **M** **W** **S** **D**

ADDRESS PHONE

HOSPITAL HOSP. NO. ROOM & WARD

PATIENT SOURCE
Cgh in • c**G**h clin • **H**olmes in • h**O**lmes out • chil**D**ren's in • chi**L**dren's clin • **J**ewish in • je**W**ish clin • o**T**her in • oth**E**r out • **P**rivate office

OCCUPATION
blue **X** • blue x & **S**hield • **N**either • **O**ther
medicare **A** • medicare a & **B** • **O**ther • **N**either

RELATIVE OF FRIEND ADDRESS PHONE

REFERRING PHYSICIAN ADDRESS PHONE

REASON FOR PROCEDURE PROCEDURE REQUESTED

NO. OF PREV. ISOTOPIC PROC. U.C. and [illegible] (9.9 or more) ☐

ISOTOPIC MAT. (See code - reverse side) ☐☐☐☐☐

DOSE UNITS **C**urie **M**c **U**c **N**c **P**c **R**units (x 10) in **V**itro n**O** dose

DOSE ☐☐☐☐

ROUTE
oral **L**iq.
ca**P**sule
Gastric tube
Rectal
Topical
in**H**alation
i.**V**.
sub**Q** or i.m.
inter**S**t. liq.
l**Y**mph
Arterial
intra**C**av. liq.
s**E**al. source?
seal. so**U**rce d
i**N**vitro test
n**O** dose

PLACE ISOTOPES ADMINISTERED
Uc med. ct.
Children's
Jewish
Elsewhere
Not applic.

DATE ISOTOPE ADMINISTERED (Zeros for no dose) ☐☐☐☐☐☐

PROCEDURES (See code - reverse side) ☐☐☐☐☐☐☐☐☐☐

CARD **1**

REPORT

ISOTOPE MAT. DOSE ROUTE DATE TIME
PROCEDURE PERFORMED

ASSESSMENTS - PHOTOSCANS (Not Scinti-Photos)

CAR
DATE SAM
SCA
Bla
SITUATIO (18)
SIZE (19)
SHAPE (20)
EDGES (21)
UNIFORMITY (22)
HOT AREAS (23)
COLD ARE (24)
TECHNICAL QUALITY (25)

RESULTS
RESULTS (P
n**O**t
n**0**
RESULTS
n**O**t
n**0**

Fig. 2. Patient information portion of radioisotope laboratory patient form

Average doses were calculated using the beta-gamma formulas given in Figure 3. We will concentrate here on the beta dose and on the absorbed fraction concept for the gamma dose determination. The application of these formulas requires careful consideration of certain of the parameters, namely 1) absorbed fraction, A.F., values as a function of photon energy for various cylinder sizes, values which have only become available during the past few years; 2) the concentration, C_o (in μCi/g), which indicates knowledge of the amount of radioactivity in the organ per gram of the organ (here gross assumptions concerning organ size are made in many cases); and 3) T_e, the effective half-life (in days), which involves both the physical and biological half-life. The biological half-life is largely a function of the rate of metabolism of the radiopharmaceutical by the individual and thus varies considerably among individuals. Figure 4 shows the absorbed fraction as a function of photon energy for various cylinder sizes. As far as the concentration is concerned, for some clinical procedures, e.g., thyroid uptake, the amount of activity in the organ or gland can be estimated to a good degree of accuracy. Estimates of organ size are at best crude and account for a considerable portion of the error in dose estimation. Estimates of the effective half-life can only be made from measurements on various individuals administered radionuclides. This information cannot be obtained by the administration of radionuclides to normal individuals; therefore, this information is obtained by periodic counting of an individual administered radionuclides for a clinical procedure.

Fig. 3. Dose formulae for internal dosimetry

BETA : $D = 73.8\ \bar{E}_\beta C_o T_e$

GAMMA: $D = 73.8\ (n\bar{E}\gamma) C_o T_e\ (A.F.)$

A.F. = Absorbed fraction-that fraction of emitted gamma-ray energy absorbed by a phantom of specified mass and geometry

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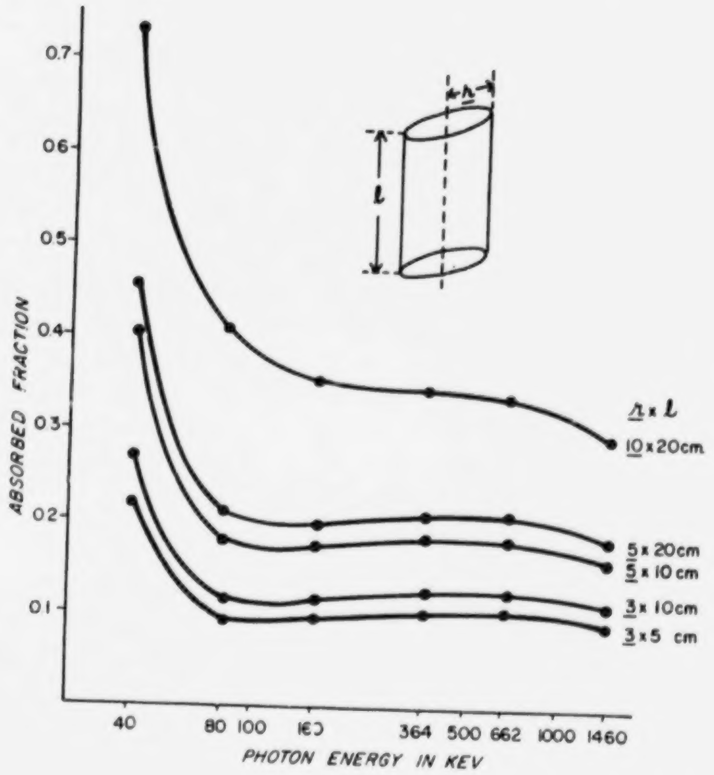


Fig. 4. Absorbed fraction as a function of photon energy for various cylinder sizes (extension of data of Ellett, et. al.) (3,4).

We would like to point out here that, during the past few years, a considerable number of these clinical procedures have been performed on children. Our group has stressed the need for dividing the infant and child population into specific groups to allow better estimates of dose (5). These groups are shown in table 1, along with information on average body weights and organ weights (6). Dose estimates for children were in many cases based on information reported for adults. Because of the possible difference between the physiological response of adults and that of children, continuing studies are being carried out by our group to obtain information on the metabolic fate of several radiopharmaceuticals in infants and children who were referred for various illnesses or because of diagnostic problems. If the radionuclide is distributed uniformly throughout the body, information on T_e can be obtained by counting the patient periodically in a whole body counter (standard chair counting position as shown in figure 5). The use of collimated crystals can provide information as to the effective half-life of radionuclides which tend to concentrate in various organs. Data such as those in figure 6, which shows serial counts of thyroid and thigh tissue over a period of time, provide information on T_e which can be inserted into the formula for dose estimate purposes. As shown in table 2, the uptake in a newborn was measured as 67 percent, whereas the thyroid uptake for other children studied ranged from 9 percent to 22 percent. Thyroid uptake values for children vary greatly. The I-131 uptake is elevated at birth; after 1 week, it returns to values in the lower portion of the normal range for older children. Doses to the thyroid in rad per microcurie of I-131 administered are also given in table 2. Since others have also reported high uptakes during the first week following birth, with an apparent reduction in the iodine uptake in the thyroid after the first week or so of life, it is recommended that radioisotope tests be deferred for this period unless the diagnostic procedure is a life-saving one. Similar studies for other radionuclides are shown in the next two tables. Table 3 shows whole body doses for Chromium-51 (sodium chromate) and Iron-59 (ferrous citrate) for children of various ages, based on observed effective half-life values. Table 4 shows radiation doses from radiopharmaceuticals such as Mercury-197 (chlormerodrin), Calcium-47 (calcium chloride) and Strontium-85 (strontium nitrate) with both whole body doses and organ doses given for children in various age groups. These doses are given in millirad per microcurie administered.

TABLE 1

Body Weights and Organ Weights for Various Ages (6)

Organ	Organ weight (grams)					
	Newborn	1 year	5 years	10 years	15 years	Standard man
Whole body	3,540	12,100	20,300	33,500	55,000	70,000
Thyroid	1.9	2.5	6.1	8.7	15.8	20.0
Kidney	23	72	112	187	247	300
Liver	136	333	591	918	1,289	1,700
Spleen	9.4	31	54	101	138	150

TABLE 2

Thyroid doses from ^{131}I (sodium iodide) in children (7)

Age	Uptake (%)	Effective Half-life (days)	Thyroid Dose	
			Observed Rad/μCi Administered*	Calculated Rad/μCi Administered**
2 days	67	4.7	23.8	32
1 month	10	7.0	5.0	10-32
3 months	9	4.2	2.7	10-32
2 years	10	5.2	2.5	4.3-10
4 years	21	6.3	3.9	4.3-10
6 years	22	4.8	2.4	3.1-4.3
15 years	16	5.9	0.9	1.7

*Based on values measured in this study

**Based on previously reported standard child groups (8)

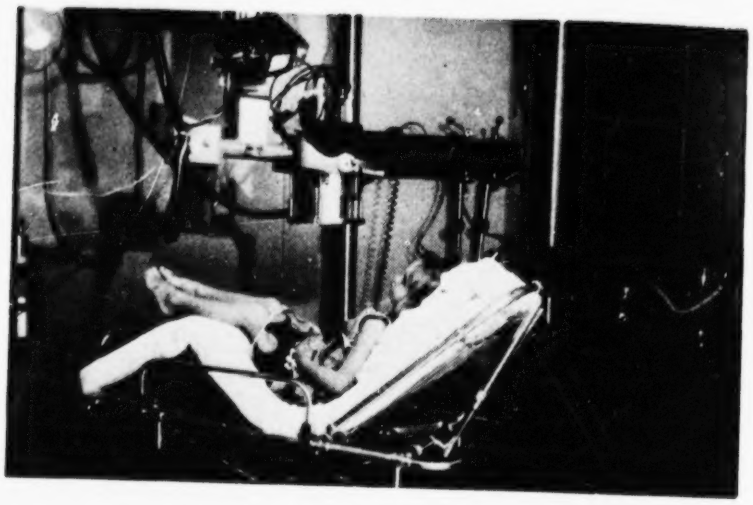


Figure 5. Whole body counting (standard chair position)

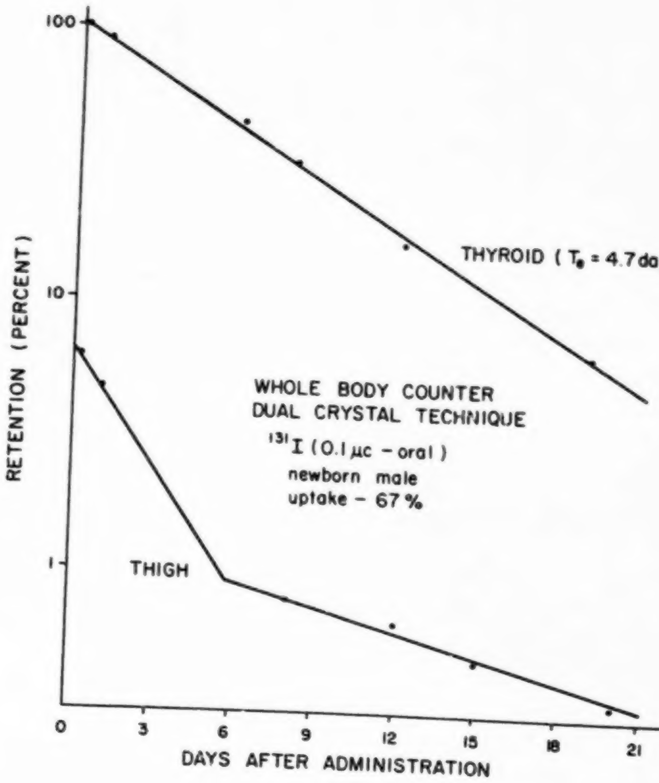


Fig. 6. ^{131}Iodine retention in newborn.

TABLE 3

Radiation Doses from Radiopharmaceuticals
in Children (7)

Age	Weight (kg)	Effective Half-life (days)	Whole-Body Doses	
			Observed mrad/µCi Administered*	Calculated mrad/µCi Administered**
		^{51}Cr (Sodium Chromate)		
4 months	8.18	15.0	1.8	4.5
14 months	12.60	20.0	1.7	1.6
5 years	20.00	20.0	1.2	1.0
6 years	13.62	19.4	1.6	0.9
		^{59}Fe (Ferrous Citrate)		
5 years	20.00	38.0	70.3	65
6 years	13.62	31.0	78.0	61
15 years	55.00	39.0	32.0	27

* Based on values measured in this study.
** Based on previously reported standard child groups (9).

TABLE 4

Radiation Doses from Radiopharmaceuticals in Children (7)

Age	Weight (kg)	Effective Half-life (days)		Doses	
		T_{e_1}	T_{e_2}	Whole body mrad/µCi Administered	Organ mrad/µCi Administered
		^{197}Hg (chlormerodrin)			
3 years	14.55	0.8	2.6	0.16	68.1 (kidney)
12 years	47.28	0.9	2.6	0.07	39.0 (kidney)
		^{47}Ca (calcium chloride)			
7 years	25.00	0.7	4.6	2.8	4.5 (bone)
		^{85}Sr (strontium nitrate)			
4 years	15.47	3.5	58.0	16.3	68.3 (bone)
10 years	32.70	1.3	44.0	6.0	40.8 (bone)
12 years	40.00	1.4	53.0	8.6	32.8 (bone)
12 years	60.00	1.5	30.0	2.5	14.0 (bone)
18 years	48.20	3.6	50.0	4.7	27.0 (bone)

With the ability to better assess the dose comes the possibility of dose reduction. In the thyroid uptake procedure, for example, a dual crystal technique, as shown in figure 7, can be used instead of the standard procedure in which a crystal is placed at 10 inches from the patient's neck. Two collimated sodium iodide thallium-activated crystals, suspended from a yoke, are brought in contact with the patient's neck. With this technique, it is now possible to carry out studies using 1/10 microcurie, or less, of I-131. Figure 8 shows the results of a series of three studies on one 3-year-old child, each using 1/10 microcurie of sodium iodide-131. The initial procedure indicated a 14 percent uptake, considered low. A repeat study after administration of thyroid-stimulating hormone indicated an increased uptake of 32 percent. The final study following administration of propyl-thiouracil indicated an uptake of 9 percent. The total dose to the thyroid gland for the three uptake procedures on this child was estimated to be 0.87 rad. Hence it is now possible to do repeated studies with low administered activities of I-131. The use of other radioisotopes of iodine, such as iodine-123, could further reduce radiation dose without interfering with diagnostic accuracy. This possibility is being investigated at the Nuclear Medicine Laboratory of the Bureau of Radiological Health by Dr. H. Wellman and Dr. V. Sodd. Iodine-123 is a particularly advantageous radioisotope of iodine because it has a physical half-life of approximately 13 hours, compared to 8.2 days for iodine-131. Since iodine-123 has no beta-particle emission and a low energy gamma ray (159 KeV), shielding requirements are also reduced. It has been estimated that the dose from a thyroid uptake procedure can be reduced by a factor of 10^4 if the standard procedure using iodine-131 is replaced by a dual-crystal technique using iodine-123.

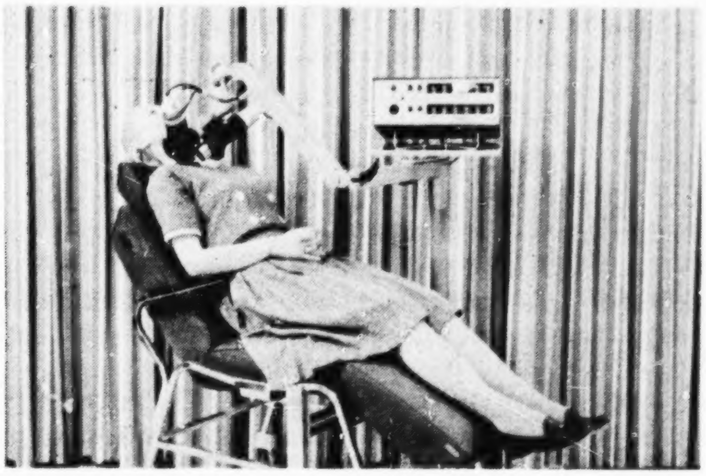
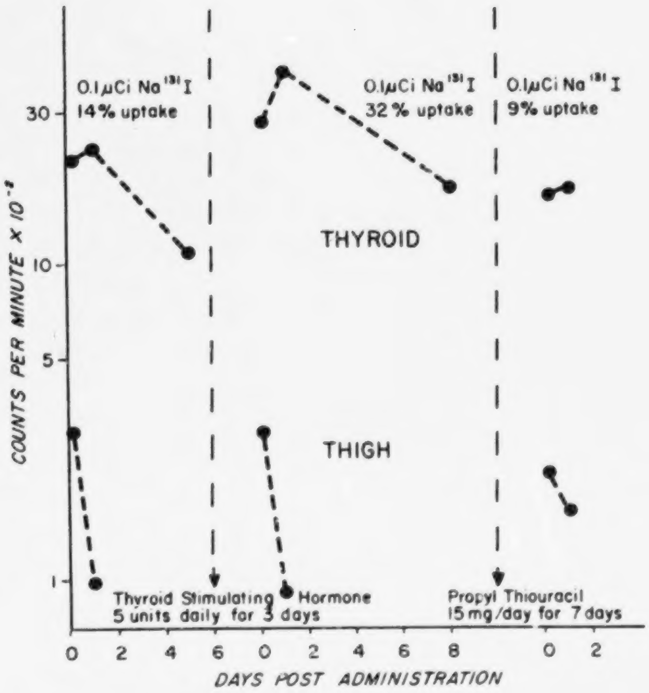


Fig. 7. Dual crystal technique for thyroid gland uptake procedure



Whole Body Counter
Dual Crystal Technique
3 year old male
Secondary hypothyroidism (low uptake, normal response to TSH stimulation, no pituitary reserve with PTU block, PBI 1.8μg)

Fig. 8. Repeated uptake procedures using low administered activities of ^{131}I (sodium iodide) (7)

The importance of the use of shorter half-life radionuclides in various clinical procedures is shown in the next two tables. In each case, the activity administered is that recommended in order to obtain the proper scan information. Table 5 compares estimated doses in rads from various radiopharmaceuticals used for liver scanning, namely, technetium sulfur colloid, gold colloid, and iodine-131 aggregated albumin. Dose to the liver from 3 mCi of technetium sulfur colloid is 0.72 - 0.99 rads, whereas 150 μCi of gold colloid results in a dose of 3.9 - 6.4 rads to the liver. Table 6 compares estimated doses in rads from various radiopharmaceuticals used for bone marrow scanning. Dose to the red bone marrow from 2.5 mCi of gold-198 colloid is 7 - 18 rads, while 5 mCi of technetium sulfur colloid results in only 0.13 - 0.17 rads to the red bone marrow.

If comparisons are to be made, there has been general agreement that the overall dose per procedure in nuclear medicine is of the same order of magnitude as that in diagnostic radiology. This conclusion was reached at the "Symposium on Reduction of Radiation Exposure in Nuclear Medicine" held at Michigan State University in the fall of 1967 (12). The present philosophy in the field is an awareness of the patient dose for the several procedures and in all instances a desire to use the procedure which will result in minimum dose to the patient compatible with the goal of obtaining optimum information. Perhaps the most fitting expression of this philosophy is Dr. Merrill Bender's statement that "the patient should not be protected out of a diagnosis."

TABLE 5

Comparison of the Dose from Various Radiopharmaceuticals
Used for Liver Scanning (11)

Radiopharm	Activity Admin	Dose Estimate (rads)					
		Total Body	Male Gonads	Female Gonads	Liver	Spleen	Red Bone Marrow
^{99m}TcS Colloid	3 mCi	0.05	0.04	0.07	0.72-0.99	0.48-1.3	0.07-0.10
^{198}Au Colloid	150 μCi	0.35	0.06	0.09	3.9 -6.4	3.7-11.0	0.4-1.1
^{131}I Agg. Alb.	150 μCi	0.02	-	-	0.09	-	-

TABLE 6

Comparison of the Dose from Various Radiopharmaceuticals Used for Bone Marrow Scanning (11)

Radiopharm	Activity Admin	Dose Estimate (rads)					
		Total Body	Male Gonads	Female Gonads	Liver	Spleen	Red Bone Marrow
^{99m}TcS Colloid	5.0 mCi	0.08	0.06	0.11	1.1-6.2	0.8-2.2	0.13-0.17
^{198}Au Colloid	2.5 mCi	5.8	0.98	1.5	51-108	62-183	7.0-18
^{199}Au Colloid	2.5 mCi	1.7	0.28	0.49	31-34	32-96	3.5-9.4

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RADIATION RECORDS-KEEPING IN NUCLEAR MEDICINE

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Introduction

Nuclear Medicine can best be defined as the diagnostic and therapeutic use of radiopharmaceuticals. The contributions of the field in aiding the diagnosis of human disease have increased exponentially in the past few years. Many pathologic states can now be determined more accurately and much earlier through the use of tracer techniques. Laboratories devoted to this area are an integral part of most major and many minor hospitals and clinics. More than 600,000 patients received a radioactive compound last year in this country alone. The great majority of patients who obtain such medical service are given small doses of radionuclides designed to delineate morphologic or functional aspects of various body organs or pools through techniques of organ imaging and tracer dynamics. Only two or three percent of the patients seen in an average hospital laboratory receive a therapeutic dose of radiation, and this most often is ^{131}I for hyperthyroidism or thyroid cancer.

Patient Radiation Exposures

Since many radioisotopes are used as gamma tags, the radiation exposures received by patients vary within a broad range (1). In the diagnostic category, patient exposure levels are presented in Table I for some of the common procedures. Brain scanning with ^{203}Hg chlormerodrin may produce as much as 40 - 60 rads of radiation dose to the kidneys. The liver also may receive a relatively high dose of 5 - 7 rads from 150 microcuries of ^{198}Au colloid. The highest exposure of all occurs to the thyroid where a typical scanning dose of 100 microcuries of ^{131}I sodium iodide is estimated to result in a 103 rad dose. The tracer studies which are not used to image a radiation field result in considerably less energy deposition. Of the frequently performed procedures, the iron turnover using ^{59}Fe chloride probably results in the highest total body dose of 200 - 300 millirads when employing a patient dose of 10 microcuries.

Table I

DOSIMETRY OF TRACER RADIONUCLIDES

Procedure	Radiopharmaceutical	Patient Dose	Dosimetry (rads)	
			Total Body	Critical Organ
Brain Scan	^{99m}Tc Pertechnetate	15 mCi	0.20	2-3 (Colon)
	^{203}Hg Chlormerodrin	700 μCi	0.14	40-60 (Kidney)
Liver Scan	^{198}Au Colloid	150 μCi	0.08	5-7 (Liver)
	^{99m}Tc-S Colloid	2 mCi	0.03	0.7 (Liver)
Thyroid Scan	^{131}I Sodium Iodide	100 μCi	0.05	130 (Thyroid)
Lung Scan	^{131}I MAA	300 μCi	0.12	2.0
	^{113m}In Fe(OH)$_3$	2 mCi	0.02	1.2
Vitamin B$_{12}$ Absorption	^{57}Co Vitamin B$_{12}$	0.5 μCi	0.002	0.08 (Liver)
Plasma Volume	^{131}I Albumin	5 μCi	0.010	
	^{125}I Albumin	5 μCi	0.006	
Iron Turnover	^{59}Fe Chloride	10 μCi	0.230	
Renogram	^{131}I Hippuran	20 μCi	0.001	0.02 (Kidney)

The therapeutic exposures encountered in Nuclear Medicine present a different situation. Our standard dose for Grave's disease in the average case is approximately six millicuries of ^{131}I sodium iodide. This results in an average thyroid radiation absorbed dose of 6000 - 9000 rads depending on gland size, uptake, and biologic turnover, and a total body dose of 1.5 - 4.0 rads. When we treat a case of metastatic thyroid carcinoma, it is our practice to administer 200 millicuries of ^{131}I if the patient is an adult. Depending on the amount and distribution of the metastatic disease, the patient under these circumstances may receive a blood dose of 75 - 250 rads (2).

Biologic Effects of Radiation

Human dose-response relationships are well worked out in many areas of medicine as in the use of digitalis for cardiovascular disorders. Danger signs of dose excess have a well defined connection to degree of toxicity, and have been described in humans as well as animals. Such information unfortunately is not available for humans from the low levels of radiation exposure encountered in diagnostic nuclear medicine. This means that either no harmful effects result from this amount of energy deposition, or the untoward results remain to be delineated. If no harm comes from these small doses of radiation, certainly some biologic effect must occur. No real insight into safe levels of radiation exposure can be found until relatively precise dose-response relationships are known at these low levels. Cytogenetic analysis as it currently exists does not seem to hold the answer to this problem since biochemical changes in the genes themselves may possibly exist without producing chromosomal aberration.

Actual and Potential Hazards

Numerous investigators have presented the association of human disease with radiation exposure (3). Some forms of leukemia have been produced in patients who have received bone marrow irradiation in excess of 50 - 100 rads with what appears to be a direct relationship of dose magnitude to incidence (4). Whether a threshold exists for this phenomenon has not been determined, but similar effects have not been observed as a consequence to the administration of tracer quantities of radionuclides. Cytogenetic abnormalaties have been seen in patients who have received ^{131}I therapy for hyperthyroidism (5), but to date no malfeasance in the recapitulation of phylogeny has been described. Thyroid nodules also may occur after iodine treatment (6), but it does not appear that there is an increased incidence of malignancy in spite of some unconfirmed work in rats to the contrary (7). During the past 20 years more than 100,000 thyrotoxic patients have received doses of radioiodine and yet the incidence of carcinoma has not exceeded that found in the general population (8). A different story might be the case if it had been the practice to treat thyrotoxic children with ^{131}I since there is convincing evidence for the production of thyroid malignancy in children who have received X-irradiation about the head, neck, or chest (9-11). When much larger doses such as the 100 - 200 millicurie amounts of ^{131}I given for thyroid cancer are employed, radiation pneumonitis, pulmonary fibrosis, acute radiation sickness, and bone marrow depression have all occurred with significant frequency but have not approached the point at which such therapy would be contraindicated (12).

If in fact significant risks are present when using radioactive compounds in tracer amounts, they are so poorly defined at present that knowledgeable dosage recommendations are impossible to make. Recent work by Russell involving radiation induced mutations in mice indicates that the risk from small doses of acute irradiation may be less than that previously estimated by extrapolation of effects from large doses into the low dose range (13). Should this be true, then even less valid information exists for evaluation of the risk in tracer methodology. One can only approach the problem utilizing the principle that the lowest possible exposures should be maintained since radiation per se does not produce any beneficial effects to normal tissue.

Patient Records

When a patient enters our laboratory for diagnosis or therapy, he is examined by a physician and a history is recorded on special forms which include any previous administration of radioactive compounds. If the patient is a child, the need for the requested study is carefully examined and only those procedures which appear to be absolutely necessary are performed. In the case of an adult, scans and tracer studies are not controlled quite as rigidly although studies which are repeated are examined very carefully for indication. The maximum number of tests which any of our patients has received would approximate four or five brain, liver, or lung scans performed over a period of one or more years. Such a patient might therefore receive a total liver dose of 30 - 35 rads and a total body dose of 0.4 - 0.6 rads spaced in time. Tracer studies such as blood volumes may be repeated five or six times during the course of a patient's illness, but these radiation levels would be considerably less. Since there are no cumulative dose limitations on the diagnostic or therapeutic use of radioactive compounds which are imposed by state or federal regulations, the question of whether to subject a patient to an additional radiation exposure is left completely to our judgment. After a patient has a procedure performed by us, the results are recorded in a permanent file along with the patient dose which was administered. Subsequent visits by the patient result in automatic recall of his old record for examination. No cumulative radiation exposure calculations are attempted except in an occasional patient who receives multiple therapeutic doses.

Somewhat of a paradox is found in the careful occupational exposure records required from Nuclear Medicine personnel. These are justified by what presumably is an overall increased risk of radiation exposure. It is doubtful that any technician would ever receive an occupational dose to the kidneys of 40 rads which many ^{203}Hg brain scans have deposited.

Reasons for Maintaining Radiation Records

Efforts to carefully document the radiation exposure to patients from nuclear medicine procedures would appear to be foolhardy at this time. Since the biologic fate of any radiopharmaceutical differs considerably from person to person, dosage calculations are often fraught with tremendous error and results vary widely even in the hands of experts. Methods of approach continue to change and have not settled into any stable scheme. An example of this is found in the internal dosimetry of children where it has only been recognized during the past few years that calculations based on adult data are often inaccurate (14, 15). Even if the appropriate mathematics were standartized and proven accurate, the delays in patient care and drain of paramedical resources into such an undertaking does not seem justified by any proven risk. The psychological barriers which are built in patient's minds whenever potential dangers in any medical procedures are expressed to the lay press must also be considered. Untold harm can be done in sacrificing potential medical benefits to many for an unproven risk to few. Those who expound on the dangers of diagnostic irradiation must be willing in their own consciences to accept the responsibility for patients who through fear exclude themselves from the benefits of such techniques. Until a satisfactory means for estimating human absorbed radiation dose, an accurate scheme for transposition of this data into biologic effects, and the true risks involved in diagnostic nuclear medicine come available, the purpose for exposure records maintenance in patients will have to remain as a means of providing rather crude information for scientists of the future.

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DISCUSSION

DR. CLIFFORD NELSON: I have a question, Dr. Collins. It pertains to the subject of history that you obtain from the patient. I'd like for you to clarify what, if any, information you want about the person's previous radiation history in terms of therapeutic or occupational radiation, and whether that would influence you in choosing the therapeutic radiation dose to be employed. For instance, this morning there was advanced a mechanism of documenting the exposure by putting a device on the person. Would that kind of information be important as a prerequisite to treatment planning or to prescribing a diagnostic radiological procedure.

DR. COLLINS: Since I'm in front of the microphone, I shall speak for therapy and ask diagnosis and radioisotopes to respond in their categories.

It seems to me that, with any patient that I can recall, the amount of radiation that I propose to give for the treatment of any cancer will exceed by so many times the amount of radiation that they may have had in the past for diagnostic or radioisotopic application that this is not apt to be significant. Had the patient had previous radiation therapy, either by external beam or by internal sources, then the dose within the tissue would rise to the level of tolerence, and would be taken into account. But, I assume you were talking here about diagnostic procedures, because the magnitude of radiation dose in therapy is apt to be of the order of a thousand times that in diagnosis. I do not at the moment consider a previous diagnostic exposure important enough to enter into my calculations, my predictions, or my prescription of radiation for therapeutic purposes.

Dr. Burdine, would you like to speak to the importance of previous diagnostic X-ray exposure in your decision to use radioisotopes?

DR. BURDINE: We pay considerable attention to any previous history that the patient has in receiving exposure of this type. But, I don't really know why, because I don't know what to do with the information that I obtain sometimes. There is not enough radiation exposure involved in these procedures to permit me to go to the literature, or to any of my friends who are expert in this area and draw any sort of dose response assumption, even in a laboratory biological system, much less in the production of human disease. So, I note this previous exposure carefully as a point of interest in the hope that a little bit later on I will be able to look at it in the light of any mistakes I have made. At the present time it doesn't really enter into the decision to use radioisotopes.

DR. REYNOLD BROWN: I think we better touch on a controversial point before we close today. That is the film badge and its need. I think Dr. Collins touched on the point that the film badge in the therapy field would not be a very reliable indicator of dose, and Dr. Kereiakes made a similar remark in the area of radioisotopes.

I would like to submit one analogy that I'd like everyone in this room to consider: two film badges were worn by a diagnostic radiologist and one received an exposure of 100 mr and the other received an exposure of 5,000 mr. I think it's obvious to everyone in this room that from this information, you could tell nothing about the examinations that had been performed, the area of the body that had been irradiated, whether this was a primary or scattered exposure, or very much else of any significance. A number of those badges would have very little validity. If you will then take this over into a specific field, namely, medical radiology done with machines, you will see that the condition under which exposure is received by occupational workers as well as by patients tends to be from a variety of examinations. The validity of the number that is generated on the film badge, while it may be true to itself, it's not a valid number for any kind of an extrapolation of any biological effect.

This is a point that we've been trying to make since the concept of irradiation raised its head. This number from the film badge is not a valid number for introduction into the concept of radiation effects. The film badge is a valuable surveillance tool, and I don't want to make a speech as to what it is. But, I want to make a very important point in the record of what it is not. It is not entitled in this context to be called a personal dosimeter. I think it is very important that this objection be introduced into the record. I think it's unfortunate that in the structure of this meeting, we don't have time to really go at this, because I know there are a lot of my colleagues with whom I disagree and for whom I have the greatest respect who would like to argue this point.

DR. COLLINS: In this regard, we hope to overcome this by earnestly soliciting a statement from any or all, on this pertinent subject as part of the discussion, or anything you think might have been left out, because we would like to augment the topic discussion in any direction that has value.

We appreciate your remarks, Dr. Brown, Is there anyone else who would care to comment with regard to film badges?

MR. ANDREW KALMYKOW: I think that this question that has just been raised is of considerable importance, particularly from the legal viewpoint. I think in a lot of areas there has been some feeling that a film badge does constitute a personal dosimeter.

And I was wondering if somebody else would care to comment on that particular aspect of the problem.

DR. COLLINS: Anybody like to comment?

A VOICE FROM THE FLOOR: In a way, I think it's unfair to enter into this discussion without allowing, perhaps, the whole evening or a whole several days for discussion and comment on that part of it. But, I personally feel that film badge readings together with other information can provide what I would interpret as a personal dosimeter. But, if we consider just the reading by itself, without the possibility of getting this other information, I would agree with the statement. But, I don't want to leave the impression that it is the intent to use a film badge alone. It is combined with other information which is usually preserved and available if need be.

DR. GORSON: This question is to the lawyers rather than to the medical section. All of us have observed over the past years as new techniques are developed, the possibility of decreasing exposure to the patient with various types of examinations. I recall about 20 years ago when I first got into this field, it was common for the magnitude of radiation to a patient to be quite high. This value was reduced and now, today, it is quite common to give a dose of less than ten microcuries. In our own institution, we range between one and ten microcuries. And although this seems to be a considerable improvement, I'm still a little concerned, because people like Dr. Kereiakes can point out to the lawyer the possibility of reducing doses by a factor of ten squared or ten to the third power. Now, my question is this. How much effort should we spend in order to reduce the exposure to the patient, when, someone else demonstrates the feasibility of such reduction. Keeping in mind, the cost of new equipment and retraining personnel. To what extent are we legally obligated to keep the exposure down as soon as the requisite techniques are developed?

DR. COLLINS: Would someone care to respond to the question?

A VOICE FROM THE FLOOR: I think, first, it might depend to some extent on whether, if no reduction were made, there was a degree of liability. You might start with that. If there were no basis for liability, even with the dose at the original level, then there may be no duty to reduce it. But, certainly, if in the general concept in which one operates there is some likelihood that the dose at the higher level, when combined with other foreseeable doses, might be excessive, then I think there would be a duty to be concerned about the routine under any circumstances. One should take into consideration the expense of doing it, the difficulty of doing it and the decrease in effectiveness that might result from doing it. Consider all these and then determine whether or not to lower the dosage.

MR. JAMES KRONZER: I would only add this to what Dean Martin says: In this area of dosage the plaintiff, the person who claims that he was injured as a result of the radiation, cannot make a case unless a person of equal skill to the doctor or scientist who makes the decision testifies that the procedure was not being done according to accepted scientific standards within the community. In other words, there's no liability that a layman can draw from the failure to immediately stay with the state of the art. He must bring forward people of comparable skill in operating technique in the same area to testify positively that the failure to meet the state of the art constitutes neglect or failure to exercise that degree of skill requisite in that scientific community.

ADMINISTRATIVE ASPECTS OF RADIATION RECORDS-KEEPING

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The hospital exists for the patient and his care, but coordinating the operation of a hospital with all the supporting services, including the maintenance of the physical plant, is an endeavor that calls for talents that are apt to be far removed from professional medical interests. The role of the hospital administrator is the same as any other chief executive officer in industry---he is to carry out the policies of the Board of Directors---which in the case of the hospital includes the coordinating of all the vast support services of today's modern hospital. In carrying out his function, the administrator will seek to relieve the physician - in so far as possible - from administrative chores that represent a diversion of specialized professional time and talent, which is very scarce today.

Along with many other functions, the administrator is concerned with records of information on hospital operation. Whatever the nature of the information required, its value and usefulness can be no better than the records-keeping system that accumulates, organizes, stores and retrieves the data that represents the available knowledge on the subject. Record-keeping is an administrative function and the hospital administrator is responsible to insure that adequate and meaningful records are maintained.

Medical radiation information is only an additional type, and not a different type, of medical information from the hospital administrator's view. This presentation is intended to describe this facet of the administrative task under four headings; Purpose, Content, Source and Specifics.

PURPOSE

In court action, wherein the hospital or a member of its professional staff is the defendant, the usual charge is negligence. Since it is the professional staff that practices medicine, the hospital's responsibility lies chiefly in providing the proper tools for safe medical practice. Radiation, along with many tools of medicine, constitutes a hazard to patients and personnel. Drugs, surgical instruments, laboratory procedures are common sources of injury and litigation; patient and personnel are hazards to themselves and to each other. Radiation, however, has been singled out for special attention by patients, public and press because of apprehension. The medical profession probably has done little to allay these fears.

In the interest of promoting safety of patients, personnel, and hospitals, the hospital administrator must know the nature and magnitude of the hazard and the measures available and in effect, to protect all three. The same records that outline the possible hazards also serve to prevent injury by accidental or unnecessary exposure.

CONTENT

The content of the record will document:

1. the existence of the hazards,
2. the nature of accident or injury that could be foreseen,
3. the protective measures in effect to minimize this risk, and
4. the surveillance procedures that would recognize the injury.

1. Existence of Hazards

All hazards have an associated possibility and probability of injury. Documentation of the sources of radiation where exposure or accident could occur is a recognition of the possibility of injury or accident to personnel or patient. The record should include location, whether movable or fixed, storage areas, method of transport, and resulting zones of possible exposure. The complete history of isotopes from receipt to disposal will define the extent and magnitude of hazards associated with radiation.

2. The Nature of Accident or Injury That Could Be Foreseen

The mystery and apprehension concerning danger of radiation are much in evidence in suits involving radiation injury. Accidental exposure may or may not result in injury, but injury real or imagined will be the reason for litigation. The claimed exposure resulting in injury may occur during a diagnostic or treatment procedure, or it may be related to radiation in an area of possible hazard. In either case, the amount of exposure can be determined by reconstructing the circumstances of irradiation. If it is determined by the radiologist and physicist that no unnecessary or accidental exposure occurred, the records of equipment, personnel, and areas of possible hazard will support his contention.

For each type of source of radiation, possible accident or injury should be foreseen and a preplanned course of action rehearsed. Preplanning can prevent minor accidents from becoming major catastrophes such as for the rupture of a radium source where mass contamination can be prevented by proper action.

3. Protective Measures to Minimize Risk

All sources of radiation should have documentation as to what protective measures are employed for protection from both inadvertant and controlled exposure. The administrator is responsible for insuring that adequate records are maintained concerning protective measures during construction or alteration of a building that will house radioactive sources. Plans for adequate protection require the cooperative efforts of radiologist, physicist, architect, contractor and administrator, but the administrator is responsible for supervision to insure that contractors meet specifications.

The administrator will insure the maintenance of records of routine protective measures including records on qualified personnel, safety devices, instruments, and safety protocols and check lists.

4. Surveillance Procedures That Would Recognize the Injury

Surveillance procedures include area monitoring and personnel monitoring. The records of personnel monitoring by film badges or dosimeters may be kept by the radiation safety officer who may summarize the information for the administrator. Records of area monitoring provide detail about the hazards that are present and probability of injury or accident. Activities and records of committees with regard to protection are other components of the administrator's record. Surveillance records not only document the kinds and amount of radiation, but also reflect any change or fluctuation with time, daily operation, and change in personnel.

THE SOURCES OF INFORMATION

The hospital administrator does not and cannot usurp the prerogatives of the physician to insure the safety of patients, but where equipment and operating personnel are often supplied by the hospital, then the hospital may share prominently in liability in the event of injury. If the hospital administrator cannot himself generate the necessary information, he can organize and plan in conjunction with the medical board and medical staff to accumulate that information through appropriate reports and surveys.

Monthly and annual reports by department heads should document the use and utilization of radiation. The radiologist may not be the sole user of radiation sources for treatment. The radioisotope laboratory may be operated by an internist or a pathologist and an increasing number of individual members of the hospital staff may use radioisotopes.

Committee reports by a Radioisotope Committee or the Radiation Safety Committee outline and document authorization of radiation and procedures in the hospital. If the need exists and such committees do not, the hospital administrator may suggest their creation by the Medical Board.

The administrator requests reports in any area of concern. The hospital administrator may ask of any department head, any committee or any staff member for information on his activities or special interests as they pertain to utilizing radiation, existence of hazards and provisions for safety.

From such sources the hospital administrator can accumulate and foster the accumulation of medical radiation information that will serve a dual function. Knowledge of danger provides the basis for establishing and maintaining effective safety measures. Carefully planned and accumulated information minimizes the onerous task of reconstructing the record when the need arises to answer a demand.

SPECIFIC RECORDS

Records should be maintained for a meaningful purpose since the maintenance of such can be very expensive. Unless more meaningful records are maintained under a new system than under an existing system, then such a change should be questioned.

In other words, more money should not be committed to record keeping unless there would be a corresponding increase in accuracy, usefulness and significance of such records being maintained.

Specific records which either are being maintained or are under consideration to be maintained at Rosewood General Hospital are:

1. Records Concerning Physical Facilities

The first important records that should be maintained are records indicating that the State Board of Health has approved the type of construction in which the radiation exposure equipment will be located.

In addition, the architect and the building contractor should state in writing that the facility has been built in accordance with the plans, and that the present physical facility meets the existing construction standards and specifications as approved by the State Board of Health.

2. Equipment Records

A certificate should be obtained from the manufacturer of the equipment stating that the machine is in safe operational condition when used in accordance with the instructions, and that the machine meets the specifications as printed on the literature published by the company.

In addition, a qualified physicist should submit records to the administrator any time a new machine is installed or a new tube is installed. Consideration should be given to having a written record of a physicist survey of the machine even after a service man has worked on the machine which might involve the tube or the filters.

3. Personnel Records

Society today demands that employers protect their employees from unusual hazards and risks insofar as possible. Therefore, it behooves every administrative person to be able to demonstrate that the institution or organization has gone beyond reasonable means to protect the employees who might be subject to radiation exposure.

If there is ever an accidental or uncalled for exposure of an employee, it is important that a record be maintained stating all the circumstances concerning the accidental exposure. The chief administrative officer should be notified immediately that an accidental exposure has occurred.

The Director of the Radiology Division should establish standards concerning employees' experience, education and background. He, of course, will want to submit routine reports to the administrator stating to the effect that all new employees who have been hired meet these standards, and that he has used due care in the selection of these employees.

4. Committee Records

The chief administrative officer of the institution should be quite concerned over the records maintained by the various internal committees. These committees may be known as Radioisotope Committee, or a Safety Radiation Committee--but regardless of the names, the chief administrative officer should receive routine reports concerning the various committee's activities.

The chief administrative officer should als receive a monthly report that there have been no known unusual radiation exposures to either employees or patients.

The chief administrative officer should also request the Director of Radiology Division to develop a protocol Manual to minimize the risks, to employees and patients, in hazardous areas. This Manual should contain such things as exposure limits, the rules, procedures for hazardous level of radiation, safety aids for hazardous zones, and radiological safety procedures. These, of course, should be spelled out in detail and a copy of this Manual, approved by the appropriate committee, filed with the Administrator.

5. Patient Records

Patient records are known as clinical records and can be divided into two categories---inpatient and outpatient clinical records.

Inpatients

Diagnostic X-ray reports will always be found as a part of the clinical record of the patient, the date of the requisition, the date the exposure was made, and the date that the film was read by the Radiologist. It will also contain other such pertinent information as the patient's name, age, etc.

There has been concern during the past years concerning the radiation risk involved in x-raying a pregnant patient. Consideration is being given presently to revising our X-ray requisition to ask the question whether or not the patient, to the best of her knowledge, is at the present time pregnant. Others have recommended that the requisition be changed to include the date of the last menstrual period--so as to insure that no radiation exposure is effected within the first ten days following the menstrual period.

On radiation therapy inpatients, it is, of course, much easier to document the exposure than it is for diagnostic radiology. The important thing to check is whether or not the radiologist is making adequate notes, summarizations, in the patient's clinical record, and whether or not there is enough evidence within the clinical record to substantiate treatment involved. Progress notes by radiologists are extremely important, indicating the progress of the patient, any symptoms, etc.

Radioisotope is to a great extent like exposures within the diagnostic X-ray department since it is more difficult to determine the amount of radiation exposure the patient has received; however, if the radioisotope records are properly documented, one can demonstrate that the amount of radioisotope consumed by the patient is within the limits as prescribed by "good medicine."

All of the inpatient records at the present time are being reviewed by the Medical Care Appraisal Committee---a committee of the Medical Staff of Rosewood General Hospital. This includes all aspects of radiation exposure. The committee concerns itself with whether or not the patient has received unnecessary tests, hence unnecessary radiation exposure. It also reviews the chart for completeness and accuracy. The Medical Care Appraisal Committee Minutes are reviewed both by the Executive Committee of the Medical Staff (Medical Board) and by the Board of Directors.

Outpatients

Only recently have hospitals begun to review, at the Medical Care Appraisal Committee level, outpatient records. Emergency Room records a few years back were not reviewed by any committee in many institutions; however, today Emergency Room medical records are being reviewed more and more by Medical Care Appraisal Committees. Within the past two years, the Medical Care Appraisal Committee at Rosewood General Hospital has begun to review the Emergency Room medical records.

A parallel situation exists concerning outpatient radiation exposure records regardless of the source. Consequently, the Medical Care Appraisal Committee of Rosewood General Hospital is presently considering reviewing these records on an outpatient basis similar to the manner in which the Emergency Room records are being reviewed.

One of the key elements about outpatient records which the Medical Care Appraisal Committee is reviewing concerns the instructions given to patients. One must be able to demonstrate that a patient received adequate instructions thereby enabling him to recognize side-effects, symptoms, etc.

Of extreme importance is the content of the medical record, particularly concerning radiation exposure. The Director of the Radiology Division will certainly want to be the focal person performing a periodic review of the content of the medical record to insure an accurate and complete record. He must be guided by what other institutions are doing, what the Joint Commission on Accreditation of Hospitals requires, what the State regulations are, etc. He should report in writing to the administrator that a review of the content of the medical record has been conducted, and he should make recommendations when indicated.

CONCLUSION

1. The keeping of radiation records is the responsibility of the hospital. The hospital administrator must insure that radiation records are being maintained.

2. Radiation records should be both medically significant and economically feasible.

3. Because of the hazards associated with radiation, good records will afford the institution as much protection from litigation as is humanly possible, although the institution is a potential target of litigation from several angles.

4. The administrator must look to the physicians and other experts in the field of radiation to determine what a medically significant system of radiation records is.

5. If records are compiled on a routine basis, one cannot help being continually aware of the hazards which exist.

CASE HISTORIES OF COMPENSATION FOR RADIATION EMPLOYEES

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During the past twenty years the number of cases alleging injury due to exposure to ionizing radiation have been steadily increasing in the courts and before bodies administering workmen's compensation laws. This is not surprising due to the fact that it has followed the growth of technology in the nuclear science field; the continuous increased industrial use of radiation sources; and a greater educated awareness on the part of the average citizen to the dangers involved in radiation exposure as well as the concern of all over the safety and health aspects of radiation; industrially, medically, and commercially. It will indeed be surprising if cases of this type do not increase at a much more rapid rate in the future.

The decisions rendered in these cases in the past have not been praised by observers as ultimates in the distribution of justice nor have they in many cases found favor among groups representing defendents or claimants, or for that matter, the scientific community. For the most part the decisions have rested on the evidence presented; primarily expert medical and scientific testimony and the exposure data available. One great difficulty is that radiation has not yet produced a disability or disease that is not also caused by some other source. A statistical game of possibilities and probabilities can in many instances greatly influence the result. In view of this, the availability, accuracy and adequacy of exposure data, including prior medical as well as industrial exposure, takes on great significance in the individual case.

In recent years a number of individuals have concerned themselves with studying and seeking solutions to the problems presented. These studies although limited in scope and varying in approach as well as solution, have all contributed to stimulating further study.

It has long been recognized that adequate factual information is essential to producing sound conclusions. In this process it is first necessary to know what information is needed and then to develop or produce the means of obtaining it. This conference on medical radiation information for litigation is indeed an essential step in better defining and moving toward a reasonable solution to problems which confront litigants today as well as in the future.

The disciplines brought together and the expertise of the participants make one question his presence here and certainly the invitation to contribute a paper significant enough to warrant consideration by this group is a challenge in itself.

In the light of this I do not intend to present the usual type of research paper with the footnotes and documentation I learned were so important to good grades in graduate school. Rather, I am going to ask you to indulge me and accept my observations based on twenty years experience in the field of workmen's compensation and more particularly on experience and knowledge gained during the past five years by a consious and deliberate study and review of over 250 compensation cases based upon radiation exposure.

Time and space are limiting factors in attempting to meet the primary objective of this conference. However, they need not be controlling in terms of a worthwhile contribution. The parts always make up a whole.

Under these circumstances I will merely attempt to confine my presentation to a statement of certain considerations in the field of workmen's compensation law, more particularly that of one involved in thos areas coming within federal jurisdiction. For our purposes here I believe it most beneficial to merely state certain principles pertinent to the subject at hand. Then describe our general federal approach to the adjudication of radiation cases, together with an outline of the basic information we attempt to secure on claims involving ionizing radiation. I have selected for presentation indetail two case studies, not only for their value in appreciating the problems involved and the purpose of the conference, but also because they have stimulated the greatest reaction, both pro and con, to the decision arrived at, by the legal, scientific, medical, and other interested groups, of any of the cases I have encountered. In addition, as time and space permitted, some more general and briefly stated case observations that might be of concern or of interest to those present here and which indeed are worthy of note in any consideration of the problem of the need, practicality, and method of maintaining and gathering of radiation information for the purpose of use in litigation.

Workmen's compensation is a highly specialized field of law. It has developed its own principles, precedents, techniques, rules, and practices all in keeping with the basic reasons for its exitence. It is not akin to tort law which is an adversary contest to right a wrong between litigants. It is not a system for assessing blame. Fault is not involved. Negligence is not a factor. Every effort is made to keep it from becoming or permitting it to involve a purely adversary type proceeding. The rules of evidence are not those of the more formal court. The system is much different than the ordinary judicial process. The requirement of proximate or "legal" cause is not a part of the compensation law. In the federal jurisdiction, as in many other jurisdictions, it is merely necessary to show that the conditions of employment caused, aggravated, accelerated or in any way adversely contributed to the resulting disability. An employer takes the employee as he finds him. The courts have consistently held that compensation laws are to be interpreted liberally in favor of the employee in view of their humanitarian purpose and that benefit of doubt is to be resolved in his favor. Compensation law has grown up around factual rules rather than legal classifications. A rule in one situation may well form a useful precedent for application in another. Most of the issues involved are medical rather than legal, however, cases are not decided on the basis of scientific certitude. (I might say much to the consternation of many in the more prominent places in the scientific and medical community.) Presumptions and inferences are attached to causes of disability in the absence of convincing evidence to the contrary. The recognized expertise of the adjudicator in evaluating evidence, employment situations, and testimony receives great weight and rarely is disturbed on appeal.

Our approach to the adjudication of radiation claims may be summarized as follows:

All cases based on a claim for disability or death involving alleged exposure to ionizing radiation are adjudicated in our central office by a few examiners who have over the years developed by training and experience, knowledge and expertise in this type of case. Each case is decided on the basis of evidence of record in that particular case. The law, our regulations, and rules contain no specific provision relating to the degree of exposure which might be deemed a "traumatic dose". We have developed no standard upon which to base a judgment that an injury might result or be presumed to result on the basis of any specific exposure rate or accumulated exposure. Guidelines developed for the purposes of safety are not considered controlling in any case. We are not concerned with what causes the particular disability in most cases but in the case we are dealing with - alone.

Our experience has involved claims based on exposures involving work around x-ray machines, both industrial and medical; nuclear explosions and fallout; isotopes used in industry and medicine; particle accelerators; radar; and other types of emmissions.

In developing the evidence in any particular case we address ourselves to the nature of the disability or disease involved. The basic information we attempt to obtain is as follows:

1. Precise descriptions of employee's work assignments, including particularly, the equipment and appliances subjecting employee to radiation exposure and the length of time he worked with or was exposed to each, covering both his exposure in the employment involved as well as all prior exposures.

2. Whether there were any uncontrolled exposure incidents and the extent of all radiation exposures. If feasible, scale drawings of the work areas showing ventilation system, storage facilities or sources of radiation, x-ray equipment, and the location of any radiation therapy areas. The shielding at the radiation sources and at the employee's work place should be described fully.

3. The standard operating procedures used for the storage, issuing, wearing, collection, developing, and recording of film badge records and breath samples, and specifying the calibrations of the instruments used. The same information should be furnished relating to any pocket ionization chamber records, if such records were maintained by the employing establishment. If specific data

are not available, a summry of the results may be submitted.

4. Readings of any continuous monitoring equipment maintained in the employee's work area for the period of his employment, with a description of the equipment, its location, and its position in relation to the employee's work area for the period of his employment, and any other records of survey or tests of radiation made in the employee's work area. Copies of reports showing film badge readings, and readings on dosimeters or pocket ionization chambers.

5. The identification of the persons who recorded and interpreted the data and their qualifications and training.

6. Complete hospital and/or medical records of all hospitalizations of the employee, either prior or current, including any blood, urine, serological and radiological tests made. This should include any and all quantitative information relating to the level of excreted internally deposited isotopes, results of breath analysis for radon (where indicated), and whole body counts done during any period of such hospital or medical care.

7. A complete and comprehensive medical history of the employee covering all illnesses or injuries for which he has received medical care at any time. This history should be in chronological order.

8. A full employment and occupational history on the employee. This should include that information which can be obtained from records as well as from the employee.

9. Copies of all medical data included in the employee's personnel folder as well as copies of all dispensary records relating to the Federal Employee Health Program at the employing establishment.

10. A complete history of previous exposure to x-ray and/or radioisotopes, whether from medical or industrial sources. This history should be in chronological sequence and should identify those exposures which are a matter of written record as distinguished from those which are based on the employee's recollection or other indefinite information.

11. A list of x-ray equipment involved in the employee's exposure showing manufacturer, model, approximate normal power level, type of tube, and description of collimating devices used. Types of diagnostic x-rays taken (such as G.I. series, chest, etc.) and quantitative data on numbers of each type involved. The location and form of safety device used such as aprons, screens, cubicles or others.

If employee was exposed to direct or stray radiation from industrial or therapeutic x-ray, details on frequency, duration and extent of exposure, types of x-ray equipment and power level for normal operation.

12. The opinions of the attending physicians concerning the relationship between the factors of employment and the disability involved as well as other expert medical opinion as required.

As we all know, determining the information needed and attempting to obtain it is not always an easy task. Obtaining it is even more difficult. Then, if we are fortunate in this regard the great problem of determining its accuracy and reliability confronts us. As sparse, voluminous, or conflicting as the evidence might be it is always necessary to evaluate it as best we can, make a finding of facts and reach a decision in a reasonable period of time.

Let us now look at some of the cases this system has encountered and the results.

CASE "A"

On August 25, 1948, the employee began work as a chemist. From June 1950 to December 1952 his duties included intermittent testing and particle size analysis of radioactive materials. His cumulative total exposure to radiation at these phases of his work was negligible. From mid-February to mid-May 1951, he was on a temporary duty assignment in the Marshall Islands and participated in studies of radioactive fallout material following a series of nuclear detonations. His duties consisted of installing test instruments in drone aircraft which flew into fallout clouds to collect particle size samples of radioactive material. Upon their return to the base he removed the equipment and prepared microscopic samples for shipment to the United States. On one occasion it was decided to obtain samples by a manned B-17. He was one of the personnel assigned to the manned flight. He sat in the bombardier's section in the nose of the plane. The plane took off about an hour after the nuclear blast. During the flight a cover over a 6-inch opening in the nose of the plane came off. He covered it as best he could with a rubberized rain hat. This did not completely seal the opening and air and radioactive particles entered the compartment. The flight records show that the aircraft travelled for 38 minutes at low levels on the fringes of the fallout areas where the radiation intensities were not more than 200 milliroentgens per hour. The entire flying time was less than two hours. Upon return from this flight, monitor counters revealed that he had a high contamination reading. Within ten minutes of landing he was started on a decontamination scrubbing which took one hour, and the readings were reduced to background level. He did not experience any ill effects during or after the flight. Background radiation levels at the base were not at dangerous levels during the period of his temporary duty assignment. Laboratory studies of personnel and domestic animals were negative for any evidence of internal exposure. For two weeks in November 1951, he also participated in nuclear tests in the United States; during this period he received 190 milliroentgens of radiation.

A physical examination, including a blood test, in September 1951 did not show any contraindication for work with radioactive materials. A series of blood tests from December 1952 to February 1953 revealed that he had an elevated white blood count. Because of this, he was removed from work which involved exposure to radioactive materials.

Precise quantitative data concerning his exposure to radiation was not available and impossible to obtain.

Because of a progressive increase in his white blood count he was hospitalized in December 1959 and in July 1960 for diagnostic studies. Thereafter, his blood count was checked periodically at the hospital's outpatient department. A strontium-90 analysis in August 1960 and a whole body count test in September 1960 were within normal limits. The diagnosis by the examining physicians was chronic lymphocytic leukemia. He remained asymptomatic and treatment was not required. He continued to work as a chemist.

He claimed that his blood condition was due to inhalation and ingestion of radioactive substances, particularly during the February to May 1951 period.

The staff physicians at the hospital and the hematologic consultant stated that his blood abnormality suggested a benign process and that its relation to radiation was questionable. The case record was reviewed by a specialist of the Division of Radiological Health, U.S. Public Health Service. He stated that the general consensus among radiologists is that chronic lymphocytic leukemia is not as likely to be charged to radiation as is another form of leukemia known as myelocytic (or granulocytic) leukemia.

After additional development of the evidence, the case record, containing a statement of accepted facts, was sent to a specialist in the field of ionizing radiation, for analysis and opinion. On the basis of his study the doctor concluded that the blood condition was not causally related to his employment. He stated that if the condition was chronic lymphocytic leukemia, it could not be associated with radiation exposure. Assuming maximum exposures to radioactive materials under the circumstances of the flight through the fallout zone in 1951, the doctor stated that even if his condition was not of the chronic lymphocytic type, it was not related to the radioactive exposures because the exposures were insufficient quantitatively to be injurious.

The employee subsequently submitted a report from a hematologist who examined him on October 31, 1963, as a private patient, and copies of letters he received from the Chairman of the Department of Medicine at a University School of Medicine, and from the Chief Radiologist of a well known hospital. The hematologist diagnosed his condition as benign chronic lymphocytic leukemia. He did not express an opinion as to causal relation. The Chairman of the Department of Medicine in reply to a number of questions posed by the employee, stated that the types of leukemia found in Japanese exposed to atomic radiation were chiefly acute and chronic granulocytic leukemias, and that the incidence of lymphocytic leukemias was not greater among Japanese who were exposed to radiation than among those who were not so exposed. He stated further that he could not speculate as to the effects or the possible relationship of inhaled radioactive particles to leukemia and "could only assume that the leukemogenic effect, if any, would most likely be related to the amount of total radiation received in some manner."

Following an interview with the employee the radiologist stated that causal relation between radiation exposure and chronic myelogenous leukemia was reasonably well established, but, in a case of chronic lymphocytic leukemia, causal relation between radiation and the disease is very uncertain. Noting that he did not develop clinical symptoms of radiation sickness immediately after the exposure, the doctor estimated that the probability of the employee's blood condition being due to radiation exposure was less than one chance in 100.

The claim was rejected on the ground that the chronic lymphocytic leukemia was not caused or materially aggravated by radiation exposure in employment.

The case was decided primarily on the medical evidence of record. All the physicians agreed that the claimant's leukemia was a chronic lymphocytic type. It was pointed out that this type of leukemia is not associated with ionization radiation exposure. The evidence most favorable to the claim was from one doctor who indicated that there was only an exceedingly remote possibility of causal relationship. In view of this medical evidence precise quantitative data concerning the employee's exposure to radiation was not deemed vital to the disposition of the claim.

CASE"B"

The employee began work as a boilermaker in August 1963. Prior to January 1965 there was no record of his having worked in any areas of ionizing radiation. There was some evidence that he did work in areas where pipe welds were x-rayed. The periods of time, frequency, duration and amount of such exposure were impossible to obtain. Between January 1965 and February 1966 there was heavy gamma radiation in his work area. Protective clothing was worn and quick trips in and out of the source area were made in an effort to avoid excessive radiation. Notwithstanding the protective measures his film badge revealed exposure amounting to a total of 5.380 rems for the period. More detailed breakdown of the exposure indicated it was as follows: September 1965 - 2.180 rems; October 1965 - 0.620 rems; December 1965 - 0.960 rems; January 1966 - 1.620 rems. There is no record of his having worked in a contaminated area after January 1966.

The employee was 24 years of age and a radiologist estimated that he had received 3 rems as a result of natural background exposure during his lifetime. He had as a youth received radium therapy for an adenoid condition. It was not possible to locate the records concerning those treatments. There were at least six and following each one he suffered nausea indicating rather high exposure. From September 1959 to January 1961 he was employed as a television repairman. He had a number of chest x-rays during his lifetime. Since September 1963 they were taken at 6-month intervals. In December 1964 his hand was x-rayed when he fractured his fingers. In March 1966 x-rays were taken when he fractured his knee.

In January 1967 he began to notice marks on his legs and body. When they did not clear up he sought medical care in March 1967. His condition was diagnosed as acute myelogenous leukemia. He was hospitalized and following admission was found to also have tuberculosis. His disease followed the usual leukemia course and he died in September 1967. Autopsy confirmed both diagnoses.

The hematologist who first saw the employee, although not furnishing a rationalized opinion, believed the cumulative dose of radiation was a factor in the leukemia. He was transferred to another hospital for special study and treatment.

The physician in charge of the case at the hospital cancer research center felt the film badge readings were misleading pointing out that at times the employee was working on his back and an area of higher radiation would strike his abdomen and the pelvic area where the badge was not usually worn. He also pointed to instances where his arms and hands were extended overhead into an area of higher radiation.

He called attention to the earlier medical exposure and expressed the view that coupled with the industrial exposure the cumulative effect greatly influenced the occurrence of the leukemia. He also discussed probabilities and the linear rise in incidence of leukemia with a total of all radiation a person has received during his life.

A consultant radiologist questioned the tuberculosis diagnosis and agreed with the diagnosis of acute myelogenous leukemia. He felt that the employee's exposure was relatively small. He doubted that the bone marrow received exposures substantially different from those indicated by the film badge data. He pointed out that this disease may occur spontaneously without apparent cause and may also arise following exposure to ionizing radiation. He stated that the characteristics of the disease when arising spontaneously are indistinguishable from those encountered when the disease is radiation produced. He expressed his opinion only in terms of probabilities to the effect that they seemed small that the disease was a result of the radiation exposure.

The claim was accepted on the basis that the employment exposure together with the prior exposure adversely influenced the occurrence of the disease in this individual.

It should be stated that a number of compensation principles were involved in the decision. The disease is of unknown etiology, differing medical views were expressed, and the relative facts and circumstances of the case strongly suggested a relationship between the disease and employment. Benefit of doubt was applied in favor of the employee. These together with others undoubtedly influenced the end result.

Although the two cases described in detail involve leukemia it should be pointed out that claims based on this disease are only a small portion of the total. A great many involve cancer, blood disorders other than Leukemia, dermatitis, lens opacities, and a wide range of other diseases and complaints.

Limitations of time and space preclude discussion of other cases in any worthwhile fashion here. To treat them in a brief or cursory fashion would be an injustice to you and would contribute little to the discussion.

A general observation in my review of workmen's compensation cases is that present methods, practices and devices do not adequately provide measurements and information concerning radiation exposure. It is extremely difficult to obtain information or measurements of an individual's medical and non-industrial exposure. Although industrial exposure information is considerably easier to obtain and of better quality in recent years, it is still far from adequate for many purposes.

I need not tell you that the better the basic information; the more adequate, accurate and reliable the exposure data; the better the conclusions and the decisions will be in a particular case. Conscientious, careful, and professional measurement of the quantum of exposure received both medically and industrially protects the interests of the employee both as an employee and human being and serves equally well to protect the interests of an employer or other interested party. The only point remaining is to decide if the time, trouble and cost involved is worth it in terms of the results we might hope to achieve.

DISCUSSION

DR. COLLINS: Well, now we're ready for some delayed discussion on many questions that have been raised, having in mind that again, the subject of the conference is medical radiation information for litigation.

We have outlined more or less comprehensively the information which is available. What use may be made of it, and how could it be modified toward providing more useful information? I trust that the attorneys will enter into this today, because much of the problem is generated by your interest and your progress in the field.

DR. BRODSKY: I'd like to direct this to Mr. Tinsley. I'm in favor of keeping as exact records as possible. Maybe to measure exact doses, but in view of the probabalistic nature, as we have discussed before, is it really hoped that we will ever have accurate enough measurements to give a very high probability of concluding that radiation causes diseases? Is it possible that we will ever recognize this in the wording of conclusions and to say, that radiation "might have caused" a disease or "probably caused" a disease instead of saying that radiation "did" in truth cause it. I mean, can we get rid of these deterministic statements in view of the probabilistic nature of the whole thing?

MR. TINSLEY: First, let me say I'm not endorsing any elaborate, radical change, or any monumental record-keeping system such as has been suggested in some quarters in the past, where we build another monument to the computers and follow every citizen from the cradle to the grave, as far as radiation exposure is concerned. Secondly, what I was attempting to do was merely to point out the type of information that would be most desirable to have. And just show you a couple of cases, and I've seen hundreds, and the information that we were able to get. Admittedly, there are other cases that have occurred some years past when record-keeping was not as good as it is. What we want to get, particularly in the negligence field, is the best information that we can, recognizing that you will come to a better solution on that basis. However, as I indicated, we are going to decide the case, anyway, on the basis of what we've got.

Even if the case is in terms of nothing positive, in terms of a great deal of disagreement of in terms of probabilities, we are going to decide it on the basis of the information we have. And this has created quite a bit of criticism in a number of quarters. Now, in the vast majority of the cases I've seen, the employee has been the one who has lost the case. There's been some question about letting the experts present their very expert views on these things in very positive facts, that it works a disadvantage, and is not meeting the purpose of this particular system. Now, whether it meets the purposes of the courts, we can ask some of the more judiciary minded attorneys. Does that help you?

DR. BRODSKY: It helps a great deal, but in view of what you said, they are generally going to determine the case in favor of the plaintiff even where there's doubt. Then, why not state the conclusion in terms of doubt; why not enter into the final statement that, "It seems that it may have had an influence on disease and therefore, we'll award the case to him"?

MR. TINSLEY: Unfortunately, from a legal standpoint, I've got to make a final finding in it.

DR. BRODSKY: Well, this is very unfortunate, I think, from a public relations standpoint to state it that way and this brings about misunderstanding.

MR. TINSLEY: Yes

DR. BRODSKY: As I said before, I don't care how good the system, to prove that radiation or anything else caused that disease is probabilistic.

MR. TINSLEY: In fact, I think in my second case, although I don't know how the compensation order read in that case, I imagine it was in very formal and concrete terms. But, if you recall, I said that it was accepted on the basis that the combined exposure, including the employment exposure, "adversely influenced" the end result. I'm sure the compensation order said "caused."

DR. COLLINS: Dr. Bushong?

DR. BUSHONG: I wonder if, on the basis of your experience, you could say whether in all of these cases, the radiation records played a minor or a major role in the adjudication of the case?

MR. TINSLEY: I think they probably played a major role where the claimant lost out; where it was decided not in his favor. And I think largely, it was reduced to the fact that we have to reconstruct what occurred. In other words, we had to go out and find out what equipment was used; get the specifications for this equipment and then get some expert; either physicist, health physicist or radiologist, to then tell us what the exposure would be at this particular point, given this particular situation. Invariably in most of the cases that this has occurred, where you had to reconstruct, the expert opinion has always been against the claimant.

DR. WILLHOIT: Let's say that we had accurate dosimetric information and we knew the exact probability that leukemia was produced and, let's say we had cases where 50 per cent probability, ten per cent probability, one per cent occurred. Now, what would be the interpretation?

MR. TINSLEY: It would be considered together with everything else we had in that file.

DR. WILLHOIT: Well, I mean, if that is the final probability result. If it had a one per cent probability of producing the defect or the disease.

MR. TINSLEY: That, in and of itself, would not be controlling in the case. However, it would be a pretty strong bit of evidence. I'm trying to avoid a discussion on probabilities, because I believe there's a very distinguished gentleman, I think, from the University of Michigan, who has been reporting and propounding a theory that we can decide all these cases on the basis of probabilities and on the basis of charts drawn up by experts. I've been trying to avoid any confrontation with him for some time.

DR. BROWN: Well, I think we've had one of the real experts in the field with us. I think 250 cases seems to me by far the largest number of radiation cases I've ever seen referred to. Mr. Tinsley, is it reasonable to ask if in your published remarks, you would handle these in whatever manner you think appropriate, such as tabulating them.

MR. TINSLEY: Yes. However, I have limitations on my time when I have to work every day and I feel guilty if I spend all my time playing with this material. However, I have been making it available to other researchers, one of whom is Dean O'Toole who has made a study of some of these cases. He hasn't seen them all.

In addition to that, the Atomic Energy Commission has had some people making a study of each one of these cases. They do intend publishing very brief case histories. I think so far, they have about 60 of the 250 that they are getting ready to publish. I believe in one study that Dean O'Toole did, he did categorize not just my cases, but many of the ones in the states and other jurisdictions together.

Yes. I'd be very happy to try to make available information on these cases. Right now, I've got a waiting list of researchers that want access to them. But, I'd be very happy to break them out in whatever way you want statistically and tell you what is involved, either by case, by disease or by the type of emission.

MR. KRONZER: Mr. Tinsley, I think you've pointed it out, but it would be helpful for the scientists to realize that you were talking about compensation determination.

MR. TINSLEY: That's right.

MR. KRONZER: When you deal in the fault field, either in the way of alleged malpractice or some claim over a nuclear incident or excessive exposure, none of these records, in the way you look at it administratively may be used unless they meet the test of records. It's an entirely different problem.

MR. TINSLEY: Correct. And in my remarks, as I pointed out, it's a completely different thing when you start dealing with courts or when you get involved in other fields. I was speaking strictly from the standpoint of the Workmen's Compensation field.

MR. KRONZER: For example, I'm sure in the cases you have reviewed, where you've taken these expert opinions, you've done that in the form of letters of narrative reports.

MR. TINSLEY: Yes. For the most part.

MR. KRONZER: You have not brought the witnesses live here before you.

MR. TINSLEY: In some of the cases, no. Some of the cases do involve an adversary-type proceeding. But, it's not the adversary type used in federal employees' compensation cases. In some cases the doctors are not cross examined; they are not questioned except in writing and they furnish a reply in writing.

In some areas, yes. For example, under our Longshoremen and Harbor Workers Defense Space Act, there, you do have an adversary presentation.

MR. KRONZER: But, when you take the accumulation of these records based on these badges, this is just a weighted judgment by an administrator.

MR. TINSLEY: That is so.

MR. KRONZER: And you're using those records without the same requirement of authenticity that we require in the court.

MR. TINSLEY: That's correct.

DR. COLLINS: We have a number of questions. May we go on.

MR. BEN WEST: I wonder if you might, for the people in the audience unfamiliar with Workmen's Compensation, take a few moments explaining that much of what you say is inapplicable in certain jurisdictions. I have in mind the recent Garner case, in which you had the uranium miners' cases that established what in effect are the rules of criminal evidence in workmens compensation cases. In New York, on the other hand, on the Bethlyn cases, we have a situation where in the absence of records, they establish the presumption in favor of the claimant.

MR. TINSLEY: That's true.

MR. WEST: And that much of what you say has application, depending upon the jurisdiction.

MR. TINSLEY: That's correct. A great deal of what I have said would primarily be applicable to federal jurisdiction. However, some of these are applicable in the state jurisdictions. However, there are very definitely many cases decided in the states for various other reasons using many different approaches.

MR. JACK SELBY: We continue to hear a lot of information on the review of radiation claims under Workmen's Compensation. Is the same amount of effort being expended in looking at other Workmen's Compensation cases in some of the other stresses that humans are coming into contact with in the course of their occupation.

MR. TINSLEY: Quite frankly, I agree with the gentleman who preceded me. I think too much attention is being paid and has been paid to radiation cases, at least, from a Workmen's Compensation standpoint. I am convinced that Workmen's Compensation administrators and commissioners will do just as they have done in many other areas, for example, the heart disease area. They are going to come up with good rules and practices that are going to take care of the problem from the standpoint of Workmen's Compensation.

I think that everybody in his lifetime is exposed to ionizing radiation and we are going to wind up scaring ourselves to deathand make all kinds of mountains out of molehills in many of these fields on the theory that it is the only solution to the problem. And I don't think it is. I get more upset with these medical opinions I get than the lack of accurate records.

DR. COLLINS: I believe Dean White had a comment a moment ago.

DEAN WHITE: Yes. I've been debating whether the question is valid or not. I know this gentleman hinted he wanted to avoid the statistical aspect of this matter, but let me raise the question like this. Suppose, based on all the information you have in your files, of whatever character, a hypothetical question was asked of an expert that accurately included all those factors and his answer was "yes, there is an increase in the likelihood of leukemia." Now, are you, as an administrator, precluded from finding differently.

MR. TINSLEY: No. We have no set standards. As I indicated, we have set no rules directing a finding. If we get an opinion of this type, or if the exposure is thus and so, then we are getting into probabilities. But we don't say in advance that we are going to accept a given probability and if it happens to fall below that, we are not going to accept it. We haven't done that. But, as I indicated, in most of these cases, the opinions you do get from the experts are expressed in terms of probabilities. And yes, we weigh them and then decide. They are not discounted.

DEAN WHITE: I'm sorry. I started to say, on some of these things, there are population studies which do give you some sort of percentage figures. They may not take into consideration all the factors that would be in your file.

MR. TINSLEY: We rarely go outside the record.

DEAN WHITE: Sure.

MR. TINSLEY: However, as I indicated, we have been developing some expertise and we do know what some of the views of the scientists and others are, and naturally, these views enter your mind when you reach a conclusion.

CDR. TEDFORD: I'm interested in the Case B.

MR. TINSLEY: That was a Navy case.

CDR. TEDFORD: It sure was. I'm interested in how you substantiated the radium therapy cases and on what basis the radium therapy that was administered to the adenoids and tonsils was determined.

MR. TINSLEY: I think in that particular case, we had a history from the gentleman. I forget the name of the hospital that was involved. We did contact them. Unfortunately, the doctor was dead,and so his records had been destroyed. However, we did have some information that he had been treated at that hospital. Nothing more. As to the number of treatments, we had to rely on the statement of the man. There was nothing to attest that he wasn't treated and it isn't up to him to prove that he was. It would be for somebody else to prove he wasn't.

MR. KALMYKOW: This is in the nature of a comment rather than a question. I am pleased, Mr. Tinsley, that you pointed out the great difference between your situation, where knowledgeable medical and other opinions are available for consultation in reaching a decision, and that existing in some other states. There the administrator must make a decision based only on the evidence that is presented to him. And in some cases, the evidence is not complete. A person may express an opinion without as much background as might be desirable in the situation. Yet, depending on the administrator, the decision may possibly be based on this opinion.

MR. TINSLEY: Again, it might be true if you were looking for scientific certitude. We would probably get the best expert we could get and bring him in. We do have access to probably the greatest group of experts in the world, and are able to ask for an opinion and give them the whole case and they know they're not going to have to be cross examined. They know they're not going to have to testify. And unfortunately, the claimant doesn't have access to that type of expertise. So, from a litigation standpoint, this has been one of the criticisms that has been made. Everything is stacked on the side of the employer, and the poor empolyee, who at this point is economically destitute, and/or ill, doesn't stand a chance. First he has difficulty in getting access to records. Many times, he doesn't even know what his exposure has been. He's totally unaware of his exposure. Nobody has told him that he was exposed. He thinks they're giving him the benefit of an examination of a gratuitous nature through a health benefits program and they just keep following him along.

So, I'm not at all convinced that it's bad justice that some of these cases have, not had the greatest experts in the world.

DR. MORGAN: I was interested in your Case A. Presumably, the case was decided against A because he died of chronic lymphocytic leukemia rather than myeloblastic leukemia which is the type that's more likely to be a direct effect of high radiation exposure. You referred to the decision in the case, in which he testified he did not see how a dose that low could cause leukemia. It wasn't evident to me that they had collected the pertinent information for the exposure on the job. If I had been called into court, I think I would have said that: "I see no evidence of the most important data which would determine the dose that this man got when part of the windshield blew out."

I would say, "What was the fecal data? What was the dose measured in his feces?"

Because, undoubtedly, there would be large particles flying through this aperture and the man had inhaled them. In all probability, he swallowed this stuff, and the feces activity would have been exceedingly high, just as in the case of the SL1 accident where the fellows ran into the dusty room.

The fecal data, I think, is the most important and pertinent and the most involved data that can be used to decide what exposure that part of the body got.

My question then, essentially, is: Suppose someone has testified that all this information would indicate that the dose this man had gotten could be presumed from the dose to his intestinal tract and this information was missing. One might have gotten an estimate of his total dose from the GI tract dose, which the fecal data would have helped establish.

MR. TINSLEY: This probably would have produced different results.

DR. HEMPHILL: Do you have any cases of non-ionizing radiation in your series?

MR. TINSLEY: Yes. I think right now we have just about every conceivable type of case, including people that have never been exposed to any type of radiation but are suffering from some type of radiation sickness--usually, they have what we are coming to call radiation neurosis.

DR. GOLDEN: How do you evaluate the person's previous exposure?

MR. TINSLEY: We try to get the opinions of experts on this, and rely almost entirely on evaluating their expert knowledge and testimony and what they say the prior exposure was or could have been.

That, again, can be expressed in doubtful terms in many instances--and you might know, that they have been treated. And they have had a lifetime of background exposure. We can estimate what this X-ray exposure would have produced in terms of this particular injury.

In the cases thus far, the earlier exposure has not been considered to any great extent. It's only been in the last couple of years that we have been paying more attention to previous X-ray exposure.

In the earlier years of handling radiation cases, hardly any attention was paid to any prior exposure, even prior industrial exposure. Only the particular exposure cited in the claim was considered. I might say, too, that in the old cases that I've looked at, the data and the practices followed are far different that what we have found existing in the last couple of years.

DR. GORSON: I really hesitate to raise the question. I think it's probable that it would take hours to discuss it, but over the past 20 years or so, people have made a number of other suggestions on how to answer the question of Workmen's Compensation, or attempt to answer it.

I think it was Dr. Robert Gold who suggested 15 years ago that it made much more sense from his viewpoint to take the money and time and effort that go into investigating these rare diseases and trying to determine something that is in fact indeterminable and to use that money, instead, to compensate all such cases, perhaps on an insurance basis.

In other words, why spend the time and effort to do something that's really impossible from a scientific viewpoint? Why not take the same amount of money and put it into an insurance system and compensate all people that come under or meet a certain criterion. This criterion could then be a non-medical one.

MR. TINSLEY: Yes. As a federal official, there's only one answer I can give to you on that: The Congress and state legislatures have decided to do it this present way. As you have stated, there have been a number of papers presented and proposals made, for solving this problem. They range from one end of the spectrum to the other, including the probability approach.

MR. KRONZER: Of course, there's a lot of relief now in the Social Security and in the situation you're talking about.

MR. TINSLEY: Well, it's just like Workmen's Compensation, in general, in this country, there have been proposals over the past 25 or 30 years to integrate it into a Social Security system, which would include temporary disability insurance, or even permanent disability insurance. It wouldn't make any difference whether you were injured as a result of your work or not. You'd still receive a certain amount of money.

And if it happened to be tied into your work, I think the European systems all provide that you get a little bit more.

DR. COLLINS: We have discussed compensation rather thoroughly. This is an area where the general rules of law do not apply. This is an area of law unto itself, so that the concern of many of the people in medicine and in science is really unjustified in many of the questions raised.

Can we go on to some of the other questions.

DR. NORMAN TELLES: If an individual has had more than one employer for whom he handled radioactive material, and this individual subsequently develops leukemia, on whom do you fix the blame? Which of the employers are you going to be able to assign it to, since, in fact, the radiation which led to the leukemia may have come at some time prior to the last employment?

MR. TINSLEY: Under the federal law, that is not a concern of the federal government. The federal government doesn't want to fix the blame or divide up the amount of the award. So, in answer to your question, the various states handle these things in various, different legal manners. Some states have a rule that the last employer is stuck with the whole thing. Other states try to divide up the pie. That would depend entirely on the system in the state or country that was involved.

What are the recommendations or the requirements of the American Hospital Association or its certifying board for the maintenance and availability of radiation records? Does anyone know?

DR. COLLINS: I can answer that. In fact, I can put it in a few closing words. They recommend that one should keep records, but there is no specification. I think Mr. Collins' efforts were directed toward better records and better recordkeeping situations in regard to radiation detection.

DR. MORGAN: I just want to comment on Dr. Collins' statement, too. He indicated, I thought, that the principal things to go on medical records were those that would provide the hospital protection from some legal action which might be taken by the exposed individual.

I would like to add to that. We should get on the record information to show that this use of ionizing radiation, provided the best possible medical information with the minimum dose to the patient. I think this would be the first requirement in setting up things to go on the medical records.

DR. NELSON: I was a bit puzzled as to whether Mr. Collins' record was an idealized system or whether it was actually in existence. The information that he suggests should be in these records about a certification of the safety of the equipment; is that maintained today?

I wonder if I could get by a show of hands from the radiologists any indication if there is such a certification system and a manufacturer or supplier is prepared to certify to the safety of his equipment when it's installed.

Is there any case of this system?

MR. JACK SELBY: There is a USASI standard that is coming out directing itself mainly, I think, to dosimeters and measuring instruments, but also requiring a program of certification by the manufacturers. I don't know when it will be out. They've got an awful lot of work to do on it.

One draft I saw of it did include quite an extensive section on certification.

DR. NELSON: Can we assume, then, that there is no certification system at the present time?

MR. SELBY: I think probably on a case by case basis there may be.

DR. J. W. HEELY: May I comment on that?

If I understand Dr. Collins' paper, it was not that the manufacturer would certify specifically to the safety per se of the equipment, but that it met the specifications as put forth in its advertising and warranty.

In other words, the equipment would perform as advertised.

DR. NELSON: You can ask the manufacturer for such a certification. Now, if he doesn't want to give it to you, that's up to negotiation.

DR. COLLINS: I think we're on a good point here.

MR. DONALD LUOTO: I'm very happy to represent one of the manufacturers, Victoreen Instruments. We do certify certain instruments to specifications as you have pointed out. It can be verified for ten years or so, for a radiation unit.

MR. BEN WEST: Just speaking a little bit more on the standard that I saw. There is a representative from the Dallas area on the committee that's preparing it and they have used a military standard in there, so there's apparently at least one standard requiring certification and defining the items that should be included in it.

I know they have quite an extensive section on temperature and humidity and pressure requirements in the certification program.

MR. KRONZER: From a private litigation standpoint, though, the only people certification could really harm would be the manufacturers. The hospital can't prevail by saying it's got a record that was properly certified. It probably would not be acceptable in a court in private litigation if they did have a certification, because an out-of-court standard is not the one that would be applied in court.

The liability of a hospital, particularly a charitable one or state-supported one, is limited to unsafe equipment or not giving the best available and proper equipment. But certification by a manufacturer would not help the hospital even if it were written in red ink six inches high.

It might hurt the manufacturer to do it and not live up to the certification. Then, you could have a direct action against the certifier.

DEAN THOMAS O'TOOLE: I think certification may be another instance of something that involves more work than it's worth. Under the spreading rules of product liability, which are being adopted by one jurisdiction after another, it doesn't matter whether a manufacturer certifies the product. It's a matter of strict liability. It has to measure up to a standard of safety when it is operated in a normal fashion, so a certificate won't protect the injured party any more than the individual operating it under the rules of product liability.

I would think that, nonetheless, the evidence that the hospital sought a certificate to that effect would be admissible and relevant on the issue of whether the hospital was negligent in the selection of its equipment and would, therefore, tend to protect the hospital from a charge of negligence causing the same injury.

But in any event, as I say, ultimate liability would be measured under the new standards in product liability.

DR. ANTOLIN RAVENTOS: I think we should establish what the practice is at this time. It is for the radiology department to be surveyed to much in the manner that Mr. Collins described, following a very definite set of rules that are promulgated by a council for radiation measurement, and as Mr. Collins said, you should keep records of the surveys. And I believe that is a situation that is adequately controlled in most hospitals now without any new program.

I'm not sure that we radiologists would believe the manufacturers, and we'd go right on doing our own surveys even if we had a certificate.

DR. COLLINS: I think the concern that has been generated in many quarters is not for the hospital that is presently properly staffed, equipped and prepared to carry out their surveys, but is rather, perhaps, the smaller places, which are very numerous, where such surveys are never carried out.

Don't you think this is the problem?

DR. RAVENTOS: I think it's a problem of hospital accreditation and hospital standards. And if the standards in the radiology department are poor, they are liable to be poor in surgery, poor in medicine, and poor in pharmacy. This should be a function of hospital accreditation and not a specific thing to be looked into by itself.

DR. COLLINS: And perhaps, as Mr. Collins suggested in this regard, it should penetrate back to the home office of the AHA. That might well result in a revision requiring all hospitals to comply with a record-keeping system more closely.

DR. GEORGE MURPHY: In the case of the Navy man who was awarded a settlement, it wasn't clear to me whether the previous radiation made the award more likely or less likely.

In other words, were you considering the last radiation exposure to be the straw that broke the camel's back or was it more analogous to a situation in which someone was shot at a number of times and only one of the bullets hit him, and the other bullets had no effect at all. I didn't understand which way the previous radiation influenced the decision.

MR. TINSLEY: It made the award more likely. Actually, we'd have reached the same result if all he had had was the recent occupational radiation exposure.

DR. MURPHY: In other words, you feel, then, that the several hundred or perhaps even a thousand rads received medically was creating a certain stress and then this five rad additional exposure exceeded the limit and he sort of snapped.

MR. TINSLEY: It influenced the injury. It contributed.

DR. MURPHY: That would seem to be a questionable way of relating the exposures.

MR. TINSLEY: As I indicated to you before, I picked these two cases because they were the two most controversial.

DR. TEDFORD: Under the circumstances, do you think it would be advisable, then, to assess patients who have received very high radiation doses such as therapeutic exposure and avoid employing these people as radiation workers.

MR. TINSLEY: That's not a decision for me to make. I'm just telling you what happened in a compensation case. The decisions as to what your employment practices should be, or whom you employ, or whom you do not employ and what rules you set up for employing a radiation worker and what rules you follow once he is employed are the responsibility of the employer.

DEAN O'TOOLE: In this connection, Ontario had a very interesting and, I think, worthwhile procedure. The Ontario Workmen's Compensation Board requires that every employer report unusual exposures to the Board. They don't wait for a claim of injury by the employee, the way these systems usually do. Instead, they make a medical recommendation based on their judgment and they issue, not orders, but suggestions that the employees be transferred to work where there is no danger of exposure.

It seems to me a very sensible kind of arrangement.

MR. TINSLEY: Agreed. Yes. It is an excellent arrangement.

DEAN WHITE: I was just going to defend Mr. Tinsley's approach. I think any employer who causes an employee to go into an exposure area would have to be charged with knowledge that anyone in that area would quite likely be exposed to some degree.

They send him in with no knowledge of his exposure history. I suppose that's the theory we would operate on.

MR. TINSLEY: That sometimes happens in a case.

DR. BRODSKY: I think this whole discussion again points up something that I've been trying to say. I guess I haven't been making it very clear.

This whole meeting today has brought out to me that, the way it's set up, Workmen's Compensation is really overemphasizing the contribution of radiation to a disease.

I want to emphasize this again, because I think it's really going to be up to the lawyers and other people who can influence doctors and others to change the system. I agree thoroughly and heartily with what Dr. Gorson said a little while ago. If we could get that kind of system, we'd get away from a lot of hocus-pocus. I want to emphasize it just once more, because apparently I didn't get it across the last three times.

I want to make very clear to the lawyers what I mean by probabilistic. Sometimes, it's not understood by the non-scientist. Let me give a little example:

I have had about 17 roentgens of exposure in my career. Every roentgen consists of more than a billion photons. That number of photons has gone through every square centimeter of my body.

That means every square centimeter of my body had had at least ten billion photons pass through. That's a lot of photons, isn't it?

I'm still standing here, am I not? Most of this exposure occurred in the early 1950's more than 16 or 17 years ago. We know that the expected latent period for leukemia is maybe five to ten years. I haven't gotten leukemia, have I? Not yet, anyway. Maybe I will, but I haven't yet.

What does this mean? This means that it's a very rare event for leukemia to occur as a result of radiation exposure. Even if I should get almost enough radiation to kill me, the likelihood of my getting leukemia still would be slight because, if you take a probability of ten to the minus six per year and multiply by 100 roentgens, you still come up with one in 10,000.

Dr. Bushong pointed out that we can look at chromosomes now and show damages at lower and lower doses. But the fact that you can show chromosome breaks at five roentgens and yet the probability of producing leukemia and other diseases is so low must mean that even though you can show these chromosome breaks, most have nothing to do with leukemia, because we can see the breaks but we don't see the leukemia.

So, therefore, a chromosome break is not ipso facto evidence of any biological defect.

As Dr. Webster pointed out, irradiation of the fetus may induce 50 times the usual incidence of defects so your rate of defects might get a little higher. But, as Dr. Willhoit pointed out, suppose it's one per cent or ten per cent or 50 per cent--it's still probabilistic.

Sometimes a Workman's Compensation case following the onset of a disease such as leukemia reveals 5 roentgens of occupational exposure added to an individual's 6,000 roentgens previous exposure. In such a case, the increased probability of disease as a consequence of the additional 5 roentgens is negligible. In fact, the previous exposure happened to be involved in helping the patient, and the associated danger of leukemia was an acceptable calculated risk that it was necessary to take.

I know in writing regulations it was considered that we should not limit a person's employment opportunity because he had previous medical exposure, because any additional probability added by the small doses he would get as a result of his occupational exposure would be extremely minute and it would be ridiculous to say that this constituted any appreciable increase in exposure to this individual.

MR. KRONZER: Doctor, let me ask you this: Is it your view, then, that it's impossible to tell either compensation-wise or private litigation-wise that it's more probable than not, taking into account all the circumstances of the exposure, that the leukemia or the blood disorder was brought about by the radiation exposure? The second question is this: Are there other experts in your field who disagree with you?

DR. BRODSKY: I'm sure there are people in this great democracy of ours who disagree with everything I'm saying.

But I'm saying it, I think I can prove it, and I'd be willing to discuss this in more detail with you. I'm not against radiation record-keeping. I love records. I'm one of the people in favor of more records. I think you should keep accurate records and measure these doses as accurately as possible.

But I do think we are getting very expensive and very ridiculous in discussing this in terms of Workmen's Compensation litigation. I think these records should be available in cases where they have any bearing, but I don't think they can ever produce more than a probabilistic situation. You can keep the records. Fine. But when we talk about compensating an individual on the basis of a very small probability or when we talk about five to ten roentgens, I think we are getting ridiculous. It's practically impossible even in the case of hundreds of roentgens to prove causation if you're talking about proof as meaning a certainty or any degree of certainty.

It's practically impossible to prove that radiation or anything else causes disease. Because we have sensitive instruments to measure radiation, I think we are getting ridiculous about radiation. Why not get ridiculous about every other carcinogen in the environment.

MR. BEN WEST: I would whole-heartedly endorse Dr. Gorson's suggestion that we be less concerned with accuracy of our court decisions in compensating radiation workers.

However, I would like to ask Dr. Gorson if this represents a change in his opinion, and (since I saw what I took to be a nod of agreement from Dr. Webster) if this represents a change in the attitude of the medical profession. As I recall, in the 1962 hearings before the Council on the Health, Education, and Welfare Committee, there was opposition by both of you gentlemen to the Price-Delinko Bill, which was a proposed act which would have been a step in the direction of a proposal such as Dr. Gorson has made today.

DR. GORSON: Yes. You're quite right, except for one thing. The objection that we have had to the Delinko Bill was based on the element of honesty. The Delinko Bill proposed to presume injury if the exposure received exceeded the maximum permissible dose. The maximum permissible dose was never defined for that purpose.

So we were against it because it presumed a medical injury. We were against presuming that some arbitrary scale constituted scientific proof of medical injury.

However, I haven't changed my opinion. I don't think we should presume anything. Let's be honest about the thing and do it on an insurance basis. In those rare diseases, we all can share the expense per individual, because it's very low.

DR. BRODSKY: I'm sure the probability of being involved in an airplane accident is much greater, and I dare say that most of us have come in here today by plane and I dare say that all of us carry insurance in one form or other, regardless of who's responsible for the air accident.

DR. GORSON: In any low-probability, but catastrophic, effect, the only sensible approach is to share the cost and not waste a lot of time in trying to point the finger at the person responsible.

After all, the man who comes down with leukemia has to be taken care of one way or the other and, as Dr. Brown has observed in a number of his questions, it's merely a matter of whose pocket you are going to take the money from. It's going to come out of somebody's pocket.

So let's do it honestly. Let's not worry about pointing the finger and making a fine scientific and medical decision. You might as well have a lottery and draw cards out of the lottery and decide whether or not the person did or did not get leukemia because of his industrial or occupational exposure. At least we'd be honest. Dr. Robert Newell and I have been unable to pin this down, but we have discussed it at some great length. Maybe I can explain a little more about the problems and also comment on the Delinko Bill.

It's really no problem to indemnify an individual. The question is: having once done this, would you be adding names to the list as time passed?

In most jurisdictions, this has been the history. The danger in the Delinko Bill was that we would shortly presume that all forms of cancer are likewise sustained in the same situation. When you get to this point, you are talking about 20 per cent of the population. This thing could also extend on beyond the time of their employment. It's a rule of law that if there are two employers, then both of them share. This was our major disagreement with the Delinko Bill. It was not a question of whether or not you wanted it for one specific disease that is admittedly rare.

While I'm up, in an attempt to give the lawyers the specific guidelines which they have long asked for, I would suggest that perhaps the time has come to make the following statement, which would be reasonably correct, perhaps, for some embryological changes: The doubling dose for most cytogenetic defects lies between 30 and 80 Rads.

Now, this figure would be the same figure arrived at by the National Academy for Genetic Studies. If you think about it for a moment, with an incidence rate of seven per hundred thousand for leukemia, it falls into the ball park of the increase of one leukemia per million per rad. And you can apply it to nearly every one of these defects we are talking about if you know the natural incidence. By selecting some figure within this range, you get some idea of the relationship of dose to this probability.

It may be more understandable for them to think in this framework rather than in the strict terms of increased incidence in a particular situation. I notice we didn't get into the statistics, on the incidence of leukemia which may be easy to use as a general indication. The common incidence is one in 10,000 and in the person that receives about 30 to 80 rads, the likelihood increases to one in 5,000.

In trying to be a witness, I have begun to use this kind of relationship, to give attorneys some kind of guidelines as to their position.

DEAN O'TOOLE: Now, from a legal point of view, I would object most strenuously to this matter of a doubling dose. This begs the lawyers' question of the point at which we compensate this particular man in the population. This particular man who is in court, you say to him, we don't compensate him.

It begs the question. But, assuming that he's going to be compensated in terms of the whole population, 50-50, or some such figure.

But, the legal question is when should we compensate the man. Maybe there would be only a slight chance in his employment that he might have been exposed and this caused it.

It is true that we use language in common, but we don't mean the same thing. The law has progressed out of history by using a fiction. I'm in favor of using fictions. It is the vehicle by which we make the transition into new decisions. And maybe, when we talk about compensation cases from your medical point of view, we are using a fiction. But, the fiction may well be justified from the point of view of general social policy. Your doubling dose may hide this policy question by assuming without discussion that we compensate only when it is more probable than not.

DR. BROWN: It's one thing for me to say that the state of the art is such that the best information I can supply is that those individuals who receive between 30 and 80 R will double the incidence of biogenetic occurrences. That just happens to be a statement of the best state of the art.

What you do with it from there on in adjudication is your business, not mine.

This is the best testimony that I can bring to you. You can't reject it, because it's the best I can bring to you. I have nothing else to give you. You will have to make of it whatever you will, but you can't discredit it by saying that that's not good enough.

DEAN O'TOOLE: I don't think it's the best you can give. It isn't even the raw data which you work with. It is itself a conclusion in this range of 30 to 80.

DR. LUSTED: I don't know why Mr. O'Toole is so worried about a range of 30 to 80. I mean, we talk about a lot of biological variations. You look at carcinogens or genetic factors in those terms. We get back to the uncertainties of biological variations to begin with. This is probabilistic.

DR. BRODSKY: There is evidence that you can explain the degree of variation just by pure, random chance, because of what I said about the rarity of the lesions or carcinogens. Some people can be luckier by a factor of two. We've got to recognize in this 20th century that we are living in a probabilistic world. And these photons interact only in rare probabilities in the body in a way that will produce these diseases. This was recognized in the world of physics years ago and I think it's time for the legal field to revise their entire thinking in this field.

DEAN O'TOOLE: It isn't the range of the data that I object to, really. I shouldn't have been trapped by that. In all of the data that you are handling on similar matters, I am here interested more in the state of the art. But, I object to the notion of "more probably than not," because this tends to assume the pretense that that is what your lawyer is talking about. The law is not probable.

We need to talk about compensating people at a much lower level of probability than more probable than not. Maybe we should compensate all these people on an insurance basis without any probability.

DR. MORGAN: Since this question of small doses came up, I would like to refer to the very interesting slide that Dr. Webster had earlier today. I thought this was a very fine presentation on patient exposure during diagnosis.

But, as I recall, one slide showed the variation between maximum and minimum dose for various typical exposures. And you gave the units, as I remember, in kilogram-rads. And as I remember, for about ten or so different typical exposures, you indicated that the variation between the maximum and minimum was about a factor of six.

As I recall, also, for the exposure to the thorax, you had a variation of about .3 to 30 kilogram rads, a factor of 100. And so, presumably, your factor of six would be just sort of an average between these typical ones here.

This brings to mind the question which may have some legal bearing, not on Workmen's Compensation, but in many other cases. What if a man had gone to a certain facility to get his diagnosis and they had used more radiation than is needed by a factor of a hundred? Maybe in some cases it is necessary to differ from one case to another by that variation, by a factor of a hundred. But I doubt it.

Suppose, though, that this facility, through ignorance, negligence, carelessness, or what-not, persisted in giving 100 times the dose that is necessary for this type of examination. I would think that should have some bearing on the case.

MR. KRONZER: But it still wouldn't answer the question that Dr. Brodsky then poses. You see, in the field of negligence or malpractice or otherwise, you must establish this question of probability. And where we've got an expert who says it is probable under the circumstances, that meets the test of probability. But you can have negligence that is not a cause. We still have to establish cause in the court.

DR. MORGAN: But we are multiplying this plus or minus six by a factor of 100 rather than a factor of two.

MR. KRONZER: Doctor, your expert is only permitted to testify or give evidence on what the probabilities are in a field. But he must not express his view with respect to this individual in terms of the gross probabilities. And I agree. We don't need an Einstein to say that is right.

DR. WEBSTER: I just want to clear up a fact.

The slide did, in fact, indicate those differences and it was a factor of a hundred for chest and there was a factor of six for abdominal exposure, which I consider to be more important, because the dose is generally much higher for abdominal exposure.

The differences in the chest probably relate to the fact that you can take one film of the chest which has a very low dose and extremely low hazard. Perhaps you could take 50 a year before you get up to background. Whereas, if you add some fluoroscopy to that, you get into a much higher dose. And that's probably why there is that discrepancy in these.

Could I speak to one other point while I'm on my feet?

It has to do with Dr. Brodsky. I think there is a fallacy in one of the attitudes that he has been taking. Not that I disagree with the general position, but he's been saying that the probability of getting leukemia is two in a million per rad which, of course, a lot of people believe.

DR. BRODSKY: Per year.

DR. WEBSTER: Per year. On a lineal hypothesis.

I don't think that's the point which really we are facing. The question we have to ask is not what is the probability that a person receiving one rad will get leukemia, but having gotten leukemia and having received one rad, what is the possibility that the leukemia is radiation-induced?

DR. BRODSKY: Is there any difference?

DR. WEBSTER: Much! To take it very logically let me give you an example:

The normal rate of leukemia occurrence in the population amounts to about 65 cases per million persons per year. Only 65 per million per year.

If everyone in the population got one rad we believe that the increased incidence of leukemia would be two per million per year. You could say then, I think, that there was one chance in 30 that a particular case of leukemia was radiation-induced.

If you multiply the dose by ten, you now have ten chances in 30, or one chance in three, that any particular case of leukemia was radiation-induced.

Those numbers look much more worrisome to me than the gross incidence rates of two per million per rad.

DR. BRODSKY: I'm sorry. I don't follow you.

DR. WEBSTER: Let me say this: You have to ask a different question from the one that you've been stressing. The question is: If you have leukemia and you have had one rad of dose, what is the probability that that leukemia was due to the one rad?

DR. BRODSKY: Well, I think you can show that it certainly is not one in 30. The probability of him having leukemia is 100 per cent if he has got it.

DR. WEBSTER: That's true, but--

DR. BRODSKY: But, the conditional probability--

DR. WEBSTER: Well, that's what I'm saying. He's--

DR. BRODSKY: The conditional probability that any time you give a rad, you'll get leukemia, is ten to the minus six.

If a man gets it, he's got it. You can't pin it on radiation just because he's got it. Radiation is just the most convenient thing that's available.

DR. WEBSTER: But I was saying that two in 65 is the probability per rad that his disease is radiation-associated.

DR. BRODSKY: I don't believe it.

DR. WEBSTER: If you believe in your theory, I mean.

DR. BRODSKY: I don't think you'd come up with that number.

I think you are just arguing possibilities.

DR. WEBSTER: I'll let it lay on the table. You think about it.

DR. RAYMOND MOORE: I don't know if any of you have ever been a participant in an adversary case. I have almost been, twice.

In the first case, I had almost no records. The case was going to court. I felt I was right, but the lawyer said "nobody is going to believe you."

The second time, it's amazing how my medical records had improved. In the second instance, I had all the data needed. Neither case became an adversary situation, but it certainly impressed upon me that, the first time, I was right and nobody would believe me. The second time I was right and had some evidence to show it. I slept a lot better the second time.

MR. TRESSLER: I don't want to throw any cold water on the discussion but, Doctor, I think this morning you started off with a precept that in the adversary system or in the field of Workmen's Compensation there must be a decision.

Now let's take this approach: I'm sure you doctors have not led such a sheltered life that you haven't heard the medical opinion that one trauma can cause a cancer. It's been raised in adversary cases and I've been on the receiving end of this. Also, diabetes has been allegedly induced from one trauma.

And I've been hooked by my medical experts because a physician agreed in front of the jury, upon questioning by the adverse attorney, that this condition could develop from a single trauma.

The probabilities that we are discussing here are pretty far afield from that, but you get down to the same situation. Figuresand statistics are very much like a lamp post. They're good for illumination and also good for drunks to lean against.

You can use them any way you want, as you pointed out, Doctor. I'd just like to point out that I think we're beating around the bush here a great deal without arriving at anything except the realization that someone is required to come to a final decision to award money or to deny it.

DR. HEMPHILL: Mr. Chairman, I'd just like to check myself out to see if I got Dr. Brodsky's message. I take it he does not intend to apply for Workmen's Compensation.

DR. BRODSKY: I'm going to hold on to my life insurance.

MR. KRONZER: Our Supreme Court this last year adopted Dr. Brodsky's theory in Texas in leukemia, that it must be established by an expert--not by the facts and circumstances--that radiation caused it more likely than not; or with more than 50 per cent probability.

DR. COLLINS: This is in the State of Texas?

MR. KRONZER: Yes, sir.

DR. COLLINS: What case was that?

MR. KRONZER: Insurance Company of North America vs. Mirele, 411 Southwestern 2nd, by our Supreme Court. But, they adopted the "more probable than not" theory in leukemia.

DR. BRODSKY: I want to make it clear, I really am a humanist. I'm not trying to deprive this poor soul of the money. What I'm saying is that something such as Dr. Gorson suggested would make much more sense. These people need to be helped; let's give them the money. But let's not delude ourselves in trying to establish causation. We would be just playing games.

Even if you knew what the dose response relationship was, and proved it, your estimate of probability would probably have variations in these small numbers.

Now, I don't want to get into this old argument, but this is a fact. We know this today. We don't need any more evidence about radiobiological dose response relationship to say this. We are just rationalizing and talking ourselves into a conclusion because we want to help this poor soul.

That's all we're doing. We're playing games. Let's realize this, because the games really are causing people to think that radiation is more hazardous than it is. I'm in favor of radiation, but I'm with Dr. Gorson. Let's keep it down to a low level. I hope I'm making myself clear.

MR. KRONZER: You are. But the problem with any sort of welfare program or benefit system is what Dr. Brown says: You broaden the base too quickly. You get to the point where you're taking responsibility for all of your cancer problems, if you don't deal with them on an individual response basis. It's dangerous legislation.

SECOND SESSION - LEGAL ASPECTS

OPENING REMARKS

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Now comes the day for the law and lawyers as we continue the exploration of the problems, hazards, and possible controls of medical radiation usage. It must be understood at the outset that lawyers operate within a system of laws in a manner substantially different from the way in which our scientific confreres operate. They seek to know, understand and operate under a set of immutable natural laws. But the lawyer, in addition to this functioning within a system of laws, also plays the role of a law giver and law maker, and so, in this sense also operates without the system of laws. This must be kept in mind as we listen to our distinguished roster of lawyers today. Some of them will speak to you as technicians, viewing their subject matter from within the present legal system; others, however, will view their topics from without the legal system, raising and discussing policy issues, and moral issues that challenge the current legal system, and may indeed demand a change in the law. So our purpose today is two-fold; one to see the law as it is today and as it applies to this issue of medical radiation records; the other, to see what the law should be as viewed from the position of a law or policy maker.

TORT LIABILITY IN RADIATION CASES

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Dr. Vincent Collins, Chairman of yesterday's proceedings, adequately defined "Torts" and the adversary system by pointing out that there must ultimately be a finding for one of the adversaries based on a finding of facts - and a preponderence of the evidence - if there is a legal basis for allowing the case to be decided on the facts.

Dean John Neibel, Chairman of today's session, has just pointed out that the system of jurisprudence has a set of rules entirely different from those applicable to science and medicine.

The law operates within a defined limited area which spells out its rules or practice, procedure, and evidence and rights - that can be changed only through legislation or judicial interpretation.

With this in mind, the fundamentals of Tort Law are simply the basics of rights, and the precept that for every right there is a corresponding duty.

As to radiation, starting in 1901 with Konrad Roentgen and in 1903 with Mme. Marie Curie, x-rays and radium began to play a part in our lives.

The discovery and acceptance of this socio-physio phenomenon is the basis of our respective professional interest in resolving some of the related problems that do and must continue to arise.

The medical problems have been most capably discussed in yesterday's program by outstanding representatives of the profession.

The demonstrative charts, graphs and pictures quite clearly depicted many of the dangers of excess exposure to invisible radiation.

It followed that John Q. Public was soon justifiably frightened, particularly because of the dread of the "unknown".

Still the recognized benefits exceeded the dangers, and the X-ray machine, fluoroscope and radium needles became more important in the daily practice of medicine and dentistry, and also in some limited phases of industry.

The legal profession quite logically applied the existing laws of Torts to the growing uses of X-rays and radium, in seeking redress for persons injured through the negligent production or use of X-rays and gamma rays.

The right to have and use the gamma ray source necessitates the duty to use it with such attentive care that others will not be injured.

Careless and irresponsible use can be even more harmful than the careless use of firearms.

With the basis of liability established, it naturally follows that members of the medical and dental professions can be held liable for malpractice under all the various legalistic theorems, for example failure to apply the recognized state of the art, or the recognized and accepted technique or procedure; failure to determine the background of the patient, including previous exposure to radiation - wanted and unwanted; failure to evaluate the patient's present physical condition, e.g. pregnancy, or sensitivity to radiation; failure to warn the patient of the dangers of the radiation to be administered; and as a final practice and protective measure, failure to get the written consent of the patient, spouse, or of the parents if a minor is to be treated. All of the aforementioned exposures to liability for malpractice suits are in addition to the doctor's liability for any obvious act that constitutes out and out negligence, even after following each of the preceding details.

Concurrently the manufacturers, distributors and dealers of source material and apparatus such as X-ray machines, tubes, timers, shut-off devices, shields and scopes are quite naturally subject to suits for damages if they are chargeable with negligence in manufacturing their product, or in inadequately describing its roentgen ray emitting powers, focal depths, properties, characteristics, dangers, and the safe and proper method of use; even with respect to technicians and other users for their own protection, and of their anticipated patients.

Product liability, liability without fault, strict liability, and res ipsa loquitur are recognized legal theories related to the field of Tort Law and when accepted in one form or another in the various courts, should be expected to be applicable to injuries resulting from ionizing radiation.

Roentgenology and radiology are as important to the field of medicine as is the scalpel; and injuries resulting from the careless or improper use of either should result in a cause of action in the persons so injured. It is only normal and logical to expect that the mysterious invisible gamma ray cannot escape the critical aim of that symbolic, blindfolded lady, - "Justice".

To complete the picture, I would be remiss if I did not mention the efforts of the representatives of the insurance industry which coincided with those of the busy scientists, doctors, and dentists, and the equally busy lawyers, along the lines I have just described.

The insurers devised "standard form" liability policies to cover hospitals, doctors, dentists, technicians, and also manufacturers, distributors, and dealers to protect them and their financial statures from dollar damages for liabilities for Torts resulting from X-ray, fluoroscope, radium and isotope sources; while covering an additional but essentially related field of law, Workmen's Compensation.

Individual insurance companies accepted these recognized hazards and contracted to pay, in behalf of their named insureds, damages in settlement of claims, or in satisfaction of judgments against their named insureds.

The policy limits for these standard risks were within the normal capacities of insurance carriers and their reinsurers.

Chronologically speaking, 41 years after Roentgen's discovery the first successful sustained chain reaction was achieved.

After Hiroshima and Nagasaki, the gamma ray, to the average person and the leaders in the fields of commerce, industry, and insurance, meant total and instantaneous destruction and financial ruin, symbolized by a giant mushroom cloud.

After the success in weaponry, President Eisenhower in 1954 initiated the "Atoms for Peace Program", with the passage of the Atomic Energy Act (68 Stat. 921 (1954), 42 USCA., Sections 2011, et. seq.).

Very little happened. The ogre of the mushroom cloud threatened financial disaster to even the most tempted and venturesome industrialists. Large corporations with expertise and know how were very reluctant to operate, even as contractors, the U.S. Government's Nuclear Facilities, despite assurances of 100% indemnity, in that they in their highly liquid financial positions would be the prime targets in litigation, rather than the "red tape protected" sponsor and principal, - "Uncle Sam".

As a result the Program failed to get off dead center until 1957, with the passage of the Price-Anderson Amendment to the Atomic Energy Act of 1954 (Public Law 85-256 85th Congress, 1st. Session (1957), 71 Stat. 576, 42 USCA, Section 2210 et. seq.).

This Amendment was designed with a two-fold purpose; 1) to protect organizations participating in the Atomic Energy Program, and 2) to protect the public by assuring that in the event of a serious nuclear accident, funds would be available for the payment of damages. (It also included provisions for review by the Advisory Committee of Reactor Safeguard, of applications for power and test reactors and the holding of public hearings on such applications for licenses).

The basic approach to the Price-Anderson Act with respect to licensed activities - primarily power reactors connected with public utilities - was to require licensees to furnish financial protection in the form of private insurance or financial responsibility, to cover liability claims up to an amount specified by the AEC; and thereafter, and in addition to require the AEC to provide indemnity protection in the amount of $500,000,000 for each nuclear incident over and above the amount of any private financial protection required of the licensee; and to limit the liability of all persons liable for any incident, to the sum of the private financial protection and the Commission's created indemnity fund of $500,000,000.

The Act did not establish any new risks of liability (except for the aforementioned limit of liability); it was intended clearly as indemnity legislation to assure the availability of funds to satisfy claims for damages up to the maximum limits so provided.

The AEC has administered the Price-Anderson Act as a regulatory matter in accordance with its established rule-making procedures. This approach has also been applied to the Commission's review and approval of the form and substance of liability insurance policies furnished as protection, (Selected Materials on Atomic Energy Indemnity Legislation - Joint Committee Prin 89th Congress, 1st Session June 1965).

With this amendment the first privately owned power reactor was installed by the Commonwealth Edison Company at Dresden, Illinois in 1957.

No single Insurance Company or group of companies was willing to write liability insurance on the nuclear hazards of the magnitude anticipated.

Consequently, the insurance industry, in meeting with the Congress and the AEC, formed Nuclear Insurance Pools for the purpose of amassing insurance capacity to meet potential damages resulting from liability due to the operation of licensed nuclear facilities. These pools are known as Nuclear Energy Liability Insurance Underwriters, or NELIA, and Mutual Atomic Energy Liability Underwriters, or MAELU. They now provide a total of $74,000,000 of liability insurance on nuclear hazards.

The insurance companies participating in these pools indicated their willingness to accept their proportionate share of liability in the event of a loss, but declined exposure to any additional source of loss that might come through the conventional or standard market involving their regular business.

As a result several distinct features were incorporated in the customary liability policies, referred to as "Nuclear Exclusions" (incorporated in all standard policies of insurance other than those covering Workmen's Compensation.)

On the other hand, to contract for indemnity on nuclear hazards the pools through their participants devised a policy unique in several aspects, for example:

1. The policy limits cover loss and loss expense. Even though the insurer agrees to investigate, negotiate, settle and defend, it does so by charging this customary service against the policy limit. The insurers in placing their assets at risk sought to limit their loss to that maximum figure of the policy, and especially to the capacity of the pools.

2. The policy, though continuous (rather than for a term), subject to annual premium charges, has no automatic reinstatement of policy limits (as do the conventional types of liability policies); hence if a loss and/or loss expense develops by reason of a claim made against the insured, the limit is reduced accordingly. Theoretically, if a series of accidents occurred involving one policy, the policy would terminate when the aggregate of losses and loss expenses equaled the stated policy limit. The Pools have a policy restoration endorsement they will issue for a nominal premium after the AEC and the Pools are satisfied the cause of the loss, if determined, has been eliminated.

3. Though the policy is continuous, it can be terminated by the respective parties, but in the event of termination, the policy remains in effect for the period of 2 years thereafter, to

permit the filing of written claims for damages incurred from an incident that occurred prior to termination. Thus a policy could be in effect for 10 years before termination, and then for an additional period of 2 years to permit the filing of claims incurred at some time during the 10 years, subject however, to any existing applicable statute of limitations that might otherwise bar the claim.

4. In effect, though not in so many words, there is an "occurrence" policy provision which limits the exposure of the Pools to their respective capacities, or the aggregate of the several policies if their total limits are less than the Pool capacities on any one occurrence, regardless of the number of policies found contractually responsible in the nuclear incident.

5. The scope of coverage in the nuclear facility form of policy is unique for the following reasons:

"Coverage A" is an adaptation of the conventional liability policy coverage for bodily injury or property damage except it deletes the restriction of "caused by accident" and broadens the coverage by substituting "caused by the nuclear energy hazard".

"Coverage B" is unique in that it covers damages to property of an insured, which property is away from, and not on the insured site as defined in the policy, just as if the off-site property belonged to some third party.

"Coverage C" is also unique in that it is designed to reimburse Workmen's Compensation carriers, including self-insurers, for compensation losses paid to workmen (including employees of the named insured), not employed at the insured site as defined in the policy. This permits subrogation but does not of itself constitute Workmen's Compensation insurance.

6. The most unique feature of the facility form of the nuclear liability policy is its broad omnibus coverage clause, whereby any person, or persons, or corporate entities, or organizations, other than the United States and its agencies, are made insureds with respect to legal responsibility for damages because of bodily injury, or property damage, caused by the nuclear energy hazard. This broad coverage picks up the lines now eliminated in the conventional liability policies by reason of the nuclear exclusion clauses incorporated therein.

Thus, the manufacturer of a defective nut or bolt who never knew where his product would be used; or of a defective part in an airplane, who never anticipated it would crash, as a proximate cause, into a giant power reactor; or a negligent airplane pilot, or intoxicated motorists, or even a vandal, or civil saboteur whose acts caused damages, would be indemnified as omnibus insureds.

7. The facility policy covers not only the facility site, defined in the policy with respect to nuclear material upon the premises, but also that discharged or dispersed from the facility or, in an "insured shipment" in the course of transportation within the territorial limitation of the policy. An insured shipment includes only source material, special nuclear material or spent fuel and waste. It is with respect to this particular feature that careful policy construction eliminates the possibility of cumulation of liability because of two or more policies, the aggregate of which might otherwise exceed the pool or pools' capacities.

It should be born in mind that the peculiarities and unusual features of the nuclear policies issued by the insurance pools, were carefully reviewed and considered and approved by the AEC, and the Joint Committee on Atomic Energy of the Congress, inasmuch as the Price-Anderson Indemnity Fund was intended to attach directly on top of insured losses, without a gap, should the losses exceed the limits of pool policies.

NELIA-MAELU insurance funds and Price-Anderson Indemnity Funds made a maximum of $560,000,000 available to private industry, and $500,000,000 to contract operators of Government facilities for the payment of thier party liability, bodily injury, and property damage losses resulting from the nuclear hazards insured against.

The Price-Anderson Act also enabled the AEC to contract with third parties (Independent Adjusters, lawyers, Doctors, including Expert Witnesses, Radio-Physicists and others) needed to assist in the evaluation, negotiation, settlement and defense of claims resulting from a nuclear incident.

The AEC has contracted with NELIA and MAELU in a lengthy detailed contract, renewed from year to year, for the "Joint Claims Committee" of these organizations to handle claims in the AEC's behalf, whether or not claims were handled for any underlying private insurance.

The expertise of this constantly ready and available group of professional claims men for any catastrophe, should such occur, made this preferable to any standby organization of government personnel that hopefully will never be called upon.

The details and mechanics of this claims handling procedure are of no importance to this discussion except to point out that the AEC intends to follow the nuclear insurance policies in the payment of losses developing from a nuclear incident.

Fear of the ogre in the mushroom cloud, by even the experts justifies constant safety measures.

One foolish mistake could easily bring about a disastrous loss especially in a highly populated metropolitan area adjacent to a large modern nuclear reactor.

The extreme care in preparing the ground rules for the issuance of licenses and permits to private industry for the use of nuclear source material laid by the Joint Committee on Atomic Energy of the Congress, by the AEC and its licensing Division, and by the Inspection and Safety Engineering Committees of the Nuclear Insurance Pools have proven beyond doubt their merit, in that in 11 years experience, since the operation of the first privately owned nuclear reactor the total number of third party liability claims for wrongful death, bodily injury and property damage can be counted on less than the fingers of two hands, and the aggregate dollar loss for all such claims, including loss expense is within $300,000.

Despite this remarkable safety record the Joint Committee on Atomic Energy of the Congress, and the AEC, for the purpose of not only assuring payment but prompt payment of Price-Anderson Indemnity Funds in addition to NELIA-MAELU policy funds to members of the public, injured or damaged and put to great hardship by reason of a National Disaster, in the form of an Extraordinary Nuclear Occurrence (referred to as ENO), have now prepared, approved and published in the Federal Register, October 31, 1968, an Amendment to the Price-Anderson Act.

The Congress feared possible delay in payment of damages to members of the public in the event of a major nuclear disaster because of reluctance by claims people of the Pools, or because of reluctance by claims people of the Pools, or because of possible technicalities raised by ambitious agents of the AEC, or the Attorney General's staff.

Originally the Congress contemplated an amendment providing for "Absolute Liability" in the event of a "National Disaster".

The insurance industry, and some member of the Joint Committee opposed this move in fear of establishing a precedent in Tort Law that could readily spread to "National Disasters on Federal Highways on long holiday weekends, or another 'Texas City explosion'".

The insurance industry resolved the problem by proposing an endorsement to their nuclear liability policies, waiving any defense in the event of an "Extraordinary Nuclear Occurrence". These policies and all endorsements are subject to AEC approval.

This procedure in its simplicity, resolved the problem, except for the difficulty in adequately defining and "Extraordinary Nuclear Occurrence".

In addition to this waiver to apply equally to the Price-Anderson Indemnity Fund, other refinements for the purpose of assuring prompt payment were then incorporated in the proposed amendment.

Briefly it encompasses the following:

1. Emergency assistance payments ... making financial assistance available to claimants immediately following a nuclear incident without requiring claimants to sign a release, or otherwise compromise their claims ... such payments shall operate as a satisfaction to the extent thereof, of any ultimate financial settlement.

2. Waiver of defense ... the Commission and the licensee on behalf of its self and other persons indemnified, in so far as their interests appear, each agree to waive:

   (a) Any issue of defense as to the conduct of the claimant, or fault of persons indemnified, including, but not limited to.

      (1) Negligence
      (2) Contributory Negligence
      (3) Assumption of the risk
      (4) Unforeseeable intervening causes, whether involving the conduct of a third person, an act of God, or the operation of a force of nature.

   (b) Any issue or defense as to charitable or governmental immunity.

(c) Any issue or defense based on any statue of limitations if suit is instituted within 3 years from the date on which the claimant first knew, or reasonably could have known, of his injury or damage and the cause thereof, but in no event more than 10 years after the date of the nuclear incident.

The waiver of any such issue or defense shall be effective regardless of whether such issue or defense may otherwise be deemed jurisdictional or relating to an element in the cause of action. The waivers shall be judicially enforceable in accordance with their terms by the claimant against the person indemnified.

The waivers shall not preclude a defense based upon a failure to take reasonable steps to mitigate damages; nor shall they apply to injury or damage to a claimant, or the claimant's property, which is intentionally sustained by the claimant, or which results from a nuclear incident intentionally or wrongfully caused by the claimant.

Nor shall the waivers apply to injury to a claimant who is employed at the site of, and in connection with the activity where the Extraordinary Nuclear Occurrence takes place, if benefits therefore are either payable or required to be provided under any Workmen's Compensation or occupational diseases law.

The Amendment sets forth the Criterion for an "Extraordinary Nuclear Occurrence" to be followed by the AEC.

If in its opinion the Commission concludes that such occurred, based on these standards it shall initiate on its own motion such a determination.

If the Commission does not make such determination within 90 days after it has been informed that such an event may have taken place, the alleged event will be deemed not to be an Extraordinary Nuclear Occurrence.

The Commission's determination of such an occurrence shall not be subject to collateral attack by any commission, governmental body or court.

It is further contemplated by reason of the amendment that there will be but one court of jurisdiction, to wit; the U.S.

District Court nearest the site of the incident, which shall have jurisdiction over all claims arising from the incident, regardless of the place of sufferance.

In the event it appears to the court of jurisdiction and the Commission that the aggregate losses may exceed the maximum liability (Price-Anderson and any pool insurance) payments will be handled on a pro rata basis as in bankruptcy procedings.

The latter amendments avoid many obvious legal difficulties that might arise due to variations and conflicts in the laws of the various states; and also avoid the pitfalls of establishing precedents in the field of Torts.

The Price-Anderson Act assuring industry of prompt payment of losses to injured members of the public, while protecting it from ruinous losses resulting from nuclear operations, has induced industry to boldly venture into the "Atoms for Peace Program".

Since January 1, 1957 over 11,000 practical uses for nuclear energy have been developed in the field of private enterprise.

Nuclear power reactors are now successfully and economically competing with fossil fuel power generators; and metallurgy, chemistry, mining, petroleum, medicine - in fact almost all industrial and scientific occupations have been advanced because of the programs success. We are now well into the "Atomic Age" and radiation in some form will affect our lives from day to day.

With respect to any revision in the field of Tort Law as it may apply to the Medical profession, I anticipate no change in its status or in the standard form of insurance protection as first outlined, except for one factor that the practicioners and technicians will undoubtedly become aware of; that being the strong probability there may have been some exposure to radiation either wanted or unwanted by a high percentage of their patients, which they as reasonable and prudent practitioners must bear in mind, and check before subjecting these individuals to additional X-rays or gamma radiation for diagnostic or therapeutic treatment. Likewise they upon subjecting their patients to radiation for their mutual protection should record the length and detail of "R" exposure in records of their own, with copy to their patient and, copy to some central record keeping bureau of city, county state or federal status.

The reasons for this duty in conjunction with this right are twofold and quite obvious and will be discussed further as the different aspects of law with respect to radiation are discussed in greater detail in this program.

FIXING RESPONSIBILITY FOR RADIATION INJURIES STEMMING FROM MULTIPLE SOURCES

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Some of the basic problems suggested by this title have long been with us. Their most frequent modern manifestations have been in automobile accident and water and air pollution cases involving multiple defendants. Many of such cases have been litigated and courts have often been in disagreement on the theory or basis to be used and have disposed of the cases before them with varying degrees of justice and injustice. While injuries caused by radiation present novel elements that will complicate their just disposition, it might be well as a starting point to examine generally what the common-law courts have done with our problems' predecessors.

The situation which presents the simplest legal problems is that where two or more persons negligently or intentionally act in concert to produce a particular result. While there may be difficult problems in establishing whether the parties were acting in concert, once that is established, each actor will be liable for the entire result, and this will be true even though the amount of the injury inflicted by each actor is separately identifiable. The interest and purpose of the actors are as one and the law charges them with the status of a mutual agency. What each does he does for the other as well as for himself, and no policy reason exists to apportion the damages between them even where there might be some rational basis on which to do so.

A second type of situation is where two negligent defendants act independently, either successively or concurrently, to cause a single indivisible injury and, though the negligence of either alone could have caused the total injury, it cannot be determined from the evidence whether only one did so. Here again each of the defendants is held liable for the total result. Since the defendants acted independently, policy suggests that it would be desirable to determine the damage caused by each and to hold each liable for only that damage, but practical problems of proof and administration prevent the courts from accomplishing that desirable end. As between the wrong-doing defendants and the innocent plaintiff, it is better that each defendant be liable for the total sum than that the plaintiff fail in his cause of action because of his inability to establish the amount of damages caused by each defendant.

A third type situation has been litigated. Here each negligent defendant acts independently. The evidence establishes that only one of the defendants caused the injury, but the evidence does not establish which of the defendants did so. A case of this type involved two defendant hunters each of whom negligently shot in the direction of plaintiff using the same size shot, and one unidentifiable pellet landed in the plaintiff's eye.[1]

It was clear that while either defendant could have caused the injury, only one of them did so, but it was impossible to tell which one inflicted the damage. If the plaintiff's right of recovery had been made to depend upon production of evidence by him as to which defendant actually caused his injury, he would have gone uncompensated and two negligent defendants would have escaped liability. Faced with that dilemma, the court found the defendants jointly and severally liable.

A fourth type of situation involves two negligent defendants, each of whom caused some, but not all, of a single indivisible result, and the evidence provides no rational basis on which to determine the amount, or any reasonable estimation of the amount, of damages caused by each. Under these circumstances the courts again have held the defendants jointly and severally liable for the total damages. This is a result the courts have not relished, however, and if there is any logical basis on which the damages can be apportioned, such basis will be used.

A fifth type situation involves defendants who act independently, each making a contribution which alone would cause no damage, but which, when combined with the de minimis contributions from other independent sources, produces a single indivisible injury to plaintiff. Obviously, plaintiff's rights have been invaded, but, unless defendants are held strictly acountable, it seems the plaintiff would have no right of recovery unless he can, in some manner, make negligent the conduct of one or more of the defendants. One definition of negligence is that one does that which a reasonably prudent person would not do under all the circumstances. Some courts have held a defendant negligent under these circumstances on the theory that he could reasonably foresee that there would be other contributors to the condition producing the plaintiff's injury making him negligent when, in the light of such knowledge, he made his contribution. What would be reasonable if he were the only actor on the foreseeable scene becomes unreasonable in the light of the knowledge he has of the actions, or potential actions, of others. If however, the basis of the cause of action is negligence, and if each defendant in making his de minimis contribution did not know, and had no reason to know, others would enhance the injurious agent to a harmful degree, then there would seem to be no basis short of strict liability for holding anyone of the defendants liable.

The foregoing is a sketchy treatment of the approach the common-law courts have used in fixing the responsibility for injuries emanating from multiple sources and involving more or less tangible substances. In order to evaluate the adequacy of the present common law approach for the solution of the problems raised by radiation injuries, it is desirable to examine the unique characteristics of radiation injuries and the problems they pose.

The extent of the difficulties which will be added because of the unique characteristics of radiation injuries will be substantially affected by whether the jurisdiction involved applies a doctrine of strict liability

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1. Summers v. Tice, 199 P.2d 1 (Calif. 1948).

or confines recovery to situations where plaintiff can establish negligence on the part of the defendants. My prediction is that courts will adopt strict liability for industrial and commercial operations and negligence where radiation is incidental to a service, notably medical.

Some of the unique features of radiation injuries contributing to the difficulties in establishing negligence and causation, particularly where there are known or suspected multiple sources, include the following:

1. There are substantial differences in sensitivity to radiation between age groups, between individuals within those groups, and between the organs of the same individual, and the sensitivity of any person or his specific organs may vary with the recency and intensity of prior exposures.

2. The effects of radiation are cumulative, in some measure at least, in producing certain harmful consequences. This is particularly significant where injury-producing radiations have emanated from multiple sources. This cumulative characteristic permits irradiations widely separated in both time and space to contribute to a single indivisible injury. This will obviously enhance the plaintiff's problems of proof in multiple source cases on the issues of negligence and causation, but it presents still further problems. He might find that some of the defendants among those causing his exposure had varying degrees of justification. For example, a doctor with knowledge of prior radiations might realize that further exposure by radiation treatment could cumulatively result in over-exposure, but still feel justified in proceeding because of the urgency of the treatment being applied. Further, one or more of the sources in a multiple exposure situation might have obtained disclaimers while others had not. Should the disclaimers be upheld, and, if so, should the total damages be visited on those who do not have them? Similar complications might develop from one of the sources being a top secret operation where proof of what actually occurred could not be made available. If this top secret unit is a strongly suspected source, but proof cannot be made, what effect, if any, should this have on the liability of the other contributors of radiation, or the percentage of the damages to be shared by each? Should the remaining defendants bear the total loss? Further, the prior exposure may have been beyond the statute of limitations in the applicable jurisdiction. If it is applied to preclude action against the first source of radiation, should the second source be liable for the total damages? In all these cases the damages could be very great and might, if answers to these questions are "yes", fall on one whose radiation dosage was comparatively small.

3. Radiation effects are not only cumulative but emergence of injuries from them may be staggered over long periods of time. This increases the possibility that defendants in multiple source injury cases may be found in different states. From this, a whole host of problems could arise. One of the jurisdictions might allow joint and several liability against defendants producing a single indivisible injury under the circumstances involved, while another of the jurisdictions might not. Is plaintiff to be permitted by his choice of jurisdiction to inflict the total damages on one source only? Again, one of the states might require a plaintiff to prove negligence

while another might apply strict liability. Assuming the strict liability jurisdiction coincided with the one that allowed joint and several liability, should a plaintiff by making a choice among jurisdictions be allowed to recover all of his damages against one of the defendants simply by proving the necessary elements of strict liability? What would be the consequences for contribution among those causing the injury under these circumstances? Further, states vary widely in their recognition of such defenses as disclaimers, contributory negligence and assumption of risk. Still another variation in state laws that might be most significant involves statutes of limitations. In most jurisdictions the limitation period for bringing tort actions in two years, but there are substantial differences in the way those limitation statutes are applied as disclosed by the paper of Professor Cox. So if more than two years after his exposures plaintiff suffers a delayed injury, it may be barred by limitation in some jurisdictions and not in others. So until something approaching uniformity in statutes of limitations and their application occurs, as well as in these other matters, grave injustices as between multiple-source, multistate defendants could occur simply by the plaintiffs' choice among jurisdictions.

4. Within the range of its reach, radiation pervasively blankets the area substantially in all directions. Within the area of radiation, there will be people of widely varying relationships to the actor. Some may be trespassers, some licensees, some invitees, and others just members of the general public. Under the common law, the duty owed to these persons varies from very little to very much.

5. Radiation is noiseless, tasteless, invisible, odorless and touchless, except in immediately serious dosages. This will add to plaintiffs' problems of causation proof because weeks, months, or even years later, one may, for the first time, be aware of the need of knowing exactly where he was at a given hour on a given day. It will be important to know this because of the factors of distance, wind direction and the varying degrees of shielding provided by the situations into which a plaintiff might move in the course of a particular day, or over a period of days.

6. Radiation is one of the most likely causes of certain types of injuries. Among these are: (1) pre-natal, either genetic or post conception; (2) sterility; (3) increased susceptibility to disease; and (4) shortened life span. States vary substantially in their recognition of causes of action for these injuries. This will present problems in cases of injuries emanating from multiple sources located in different states, particularly where the injuries depend upon the cumulative effects of radiation.

7. Often, the effects of radiation are long delayed and this includes some of the most serious consequences of it. Such effects have been known to manifest themselves as much as thirty years after exposure. This adds to the difficulty of proof. Consider the plaintiff who learns, three months after the event, that he may have been irradiated from a certain source. He does not know whether the effects will be injurious and, if so, to what extent. He feels all right at the time and either does not have

the money to spend, or does not believe the spending of it to be justified, to hire a lawyer and a scientist to conduct for him the necessary investigation. Lawyers, because of the small chance of ultimate recovery, would not be very enthusiastic about doing substantial work on the case on a contingent fee basis. So the evidence is not obtained, but eight years later plaintiff discovers he has leukemia. The sources and means of proof have then become obscure and, in some cases, no doubt unabailable. The extent of the problem here is, perhaps, unmatched in any other type case.

8. Apart from those cases where the dosages are heavy and the effects are immediate and visible, or otherwise subject to prompt diagnosis by existing methods, radiation cases present almost insuperable problems of proof on another aspect of the issue of causation in fact. Radiation dosages known to increase substantially the likelihood of a particular disease, may not create more than one chance in ten thousand that the disease will in fact occur. In such a case, even if plaintiff knows he has been exposed, knows the source of the exposure, and can prove negligence where that is required, he still has no immediate cause of action for more than nominal damages. No expert would testify that it was "more probable than not" that the plaintiff would experience the disease. Even if some years later the plaintiff actually incurs the disease, he may not be able to prove cause in fact. Many diseases that are made more likely by radiation also happen to us naturally. So unless the radiation to which the plaintiff was exposed more than doubled his chances of getting the disease, he could not meet the minimum requirements of proof for causation in fact. This is because to meet such requirements, the plaintiff must present evidence from which it can be found that defendants conduct "more likely than not" caused his injury.

The problems presented by the foregoing unique characteristics of radiation injuries exist to some extent in connection with other personnal injuries, but in no other do they have such magnitude and complexity. In comparatively simple automobile litigation, we have come to search diligently for simpler and speedier methods of disposing of our great mass of cases. If the use of radioactive materials becomes commonplace and radiation injuries numerous, we will have a mass of radiation cases which will be much more complex, obscure and difficult than is presented by the automobile cases. Substantive common law and procedure will be inadequate to handle them. We had better learn from the automobile experience and take measures now to avoid a similarly hopeless situation.

A comprehensive proposal for handling radiation injuries is that of Professor Estep of the Michigan Law School. [2] The core of his proposal is a contingent injury fund from which all persons experiencing nonspecific injuries statistically related to radiation would be paid. It would be necessary to compensate the natural incidence cases as well as those radiation caused, since there is no way to distinguish them. The basic features of this plan are contained in this statement.

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[2] Estep, Radiation Injuries and Statistics: The Need for a New Approach to Injury Litigation, The Ins. Law Jour. 87, 103 (1961)

> "Under the fund concept, once the fact and the amount of irradiation and the responsibility for it are determined, however this is done, all of the defendants who irradiate others would contribute in proportion to the *increased chances* of some latent disease created by the radiation exposure legally charged to them. If the scientific determination on which the contributions were based are accurate, and *if a contribution has been made to cover the natural incidence cases*, the fund should be sufficient to permit compensation of each exposed person who actually contracts a disease later. Those who are exposed but do not get the disease would recover nothing, and the contributions made for them would be used to compensate fully those who do. This permits the law to provide compensation only for those who are damaged and to make a fair charge to each defendant based on the increased risk caused by him. When liability and amount of contribution are determined and the defendant has paid, his liability is discharged. When the victim gets leukemia, for example, he would recover fully merely upon proof that he had the disease. Biological causation for *his specific case* would not have to be proved either at the initial determination of the fact of exposure or at the time of onslaught of the disease. The biological causation would be determined statistically and the charges to the defendants and payments to the plaintiffs would be established on the basis of the biological statistical correlation. Only the natural incidence case are unprovided for and several solutions to this problem are available."[3]
> (Emphasis by the author)

The author then discussed the pros and cons of both a government administered fund and a private insurance program. He concluded the private insurance program would be preferable. The author then considered several possible means of obtaining the contributions to cover the natural indicence cases. After rejection all other solutions, he concluded:

> "In the absence of any exposure to radiation, the cost of the natural incidence of leukemia and similar diseases is born by those who contract the disease. Because these diseases are not only non-specific but also latent, an insurance principle can be used to reach a just result. If all exposed persons who later will be allowed to recover from the fund for contracting a disease would be required to contribute to the fund a small sum to cover the natural incidence possibilities, then they would be paying for the natural incidence risks which ordinarily is their anyway and enough would be contributed to cover these claims against the fund. If all exposed persons contributed at the time of extablishing their future rights against the fund, the contribution would be very modest and within the financial capacity of most any victim. Under this plan, the defendants would pay for the number of cases their radiation would

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[3] Ibid

be expected to cause, plaintiffs would pay for the natural incidence risk which other than for the fortuitous circumstance of irradiation would be theirs anyway, and full recovery could be permitted to each exposed person who does contract the disease."[4]

The author recognizes that his proposal presents a number of difficulties, but in spite of them he concludes that his proposal could be made workable. In my judgment, his total plan would not be workable. To demonstrate why I think it would not be workable, I will discuss the problems presented, most of which he recognized and discussed, and give the reasons for my conclusion that they would make it impracticable. I will then propose a modification of his plan and explain why I think it would be workable.

The plan proposed by Professor Estep involves a two stage litigation process. The first step is to establish one as a potential plaintiff and must be taken promptly after irradiation. The second will be taken only by those who later contract one of the radiation related diseases and will be brought to establish the existence of the disease and the damages incurred. Professor Estep's plan contemplates that each plaintiff will, in some manner, establish in the first step the fact and amount of irradiation and the responsibility therefor. He recognized that problems will beset plaintiffs in making this proof, but I do not think he realized how practically impossible it would be. As a minimum, it would seem that the following would have to be established in phase one of the litigation:

1. That the plaintiff had in fact been irradiated. The proof presented here would have to be personal to the plaintiff. Here, he would have to get into such matters as how much radiation escaped, shielding, how long he was in the presence of the radiation, at what distance and many other facts.

2. Closely related to the fact of irradiation would be proof of the amount of irradiation. The proof of this fact also will have to be personal to the plaintiff since establishing that he has received a dosage above his personal tolerance level would be essential to establishing his standing to sue in the second stage of litigation. The difficulties encountered there would be similar to those encountered in proving the fact of irradiation. Proof of the amount of personal irradiation, if a major nuclear accident should happen in a large population center, has been described as "difficult and perhaps impossible".[5]

3. Proof of the source of the irradiation would have to be made. In some instances, this might be easy, but in others it might involve extreme difficulties. For example, assume five plants within irradiation distance of a cattle feeder lot in Illinois; that the cattle feeding therein are irradiated from some source; that the radioactive substance remains in the flesh, is later eaten in a restaurant in Florida and the injury manifests itself eight years later while the victim lives in New York. It then will be extremely expensive and difficult for the plaintiff to prove: Whether he was irradiated by something he ate or from some external exposure; if

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[4] Id. at 106

[5] Id. at 115

from something he ate, to identify what that something was, and, if identified, to trace its source back to a feed lot in Illinois, and, if that is accomplished, to determine which defendant or defendants irradiated the steer from which the steak came. This problem is multiplied if the ailment plaintiff has is one that could have occurred to him without any radiation and the chances of his having it are only increased by the radiation he received. Under these circumstances, it may be impossible for plaintiff to prove that it was "more probable than not" that defendants' radiation caused his injury.

4. The "increased chances" that exposed persons would have of incurring the various types of non-specific diseases known to be statistically related to irradiation would also have to be proved. This would have to be personal to plaintiff, also, not only to show that he had standing to sue later in the event he incurred the disease, but also to establish the amount of contribution to the fund that would have to be made by plaintiffs and defendants. The same difficulties would exist here that would be encountered in proving the fact and amount of irradiation. Added, would be the complications from the cumulative effects of irradiation from multiple sources and the differences in ages, sex and amounts and recency of prior exposures of each individual.

5. The range of years for each type of disease over which the latent diseases may be expected to appear would have to be established. This will be necessary, since payments from the contingency fund will be made to all exposed persons contracting the disease including those known statistically to have incurred the disease from natural causes. So, for the fund to have any chance to remain solvent, it would be necessary to establish a range of years beyond which payments for manifested diseases would not be made.

6. How much each exposed plaintiff would be required to contribute would have to be established in phase one of the litigation. Would the plaintiff contribute in proportion to his personal "increased chances" of incurring the disease as determined in his individual lawsuit, or would everyone contribute an equal amount based upon an average "increased chance" determined from a fair sampling of all potential plaintiffs? The same question exists as to the amount of contribution to be made by defendants. However this issue is resolved, the defendants will contest this in every individual case and we may get some highly incongrous results in these individually prosecuted lawsuits.

7. Each plaintiff's contribution and that of each defendant will depend upon the amount of damages to be suffered by those who ultimately incur the disease. So this will have to be established in litigation step one. Is each plaintiff to establish that in each individual case? That would seem to be necessary, but how could a plaintiff do so at a time when he did not know how disabling the disease would be if incurred, his life expectancy at the time, or his earning capacity.

What will be the inducement to potential plaintiffs to make in step one the complex, difficult and expensive proof above outlined? It seems the inducement would be extremely small. For example, in case of a major accident exposing 100,000 people with a dosage that would double their chances of suffering leukemia, we find that, statistically, there would result only 107 additional cases of leukemia among the 100,000. That would be an increased chance of approximately 1/10 of one percent. What would be the likelihood that this plaintiff with a 1/10 of one percent chance of later incurring leukemia would prosecute this difficult phase one of the litigation and make his contribution to the contingency fund? The investigation and trial would be tedious and lengthy, which means it would be very expensive. A cost of $5,000.00 would appear to be a conservative estimate, but if we reduced that by half to $2,500.00, the potential plaintiff would have to contemplate an ultimate recovery of near $2,500,000.00 to make his expenditure a reasonable calculated risk. A lawyer would not likely render the legal services in step one on a contingency basis since there would be only a one tenth of one percent chance that his potential plaintiff would ever convert to a damage-collecting plaintiff.

In my considered opinion, there is no feasible way by which a sufficient number of plaintiffs could be induced to qualify by phase one litigation to make the contingency fund statistically workable. Undoubtedly, and I am certain that Professor Estep so contemplated, many of the foregoing problems could be lessened by comprehensive legislation setting up the contingency fund. I am unable to see, however, how they could be sufficiently eliminated to make the plan workable within the broad outlines advanced by Professor Estep.

This leaves us with the question of what can be done. In my opinion, the departure from traditional common law methods of handling such personal injury actions will have to be much more drastic than that proposed by Professor Estep. My concern here is not with employee cases covered by workmens' compensation and my suggestions do not extend to them. My proposal is this: The Federal Government would require the reporting to it, and to the person or persons exposed, all intentional exposures of above established dosages, varying appropriately with the type of irradiation and its concentration on particular body areas. The government would keep a continuing and cumulative record of such exposures. In addition, on the first exposure the person would be given a card showing the amount and type of irradiation, the portion of the body exposed, the date on which such exposure occurred, and any other medically and legally significant information. This card would contain space for the recording of later exposures. The levels of irradiation which would have to be reported would likely be such that the reporting of diagnostic and much therapeutic irradiation would not have to be reported at all. The card would constitute an ever present record which could be consulted by anyone contemplating further intentional irradiation of the person involved.

The Federal Government would require, under significant penalties for failure to do so, all licensees or other persons causing accidental or incidental irradiations of any person or persons above established levels to report the same promptly to the government and to such individuals as are known to, or can be identified by, the one causing such exposure. These reports would contain such information as might be determined to be necessary for medical and legal purposes. There would also be established procedures for detecting the existence of significant excessive irradiation in population centers whether or not such instances were reported as required by law. Upon the government coming to know of any accidental exposure above the minimum established level, whether from reports or established methods of detection, it would immediately conduct an investigation, using the most scientific instruments and methods then available, to determine relevant medical and legal facts. These facts would include the source of the irradiation, the persons who had been excessively exposed, including both the fact and amount of irradiation. In view of the mobility of our population, the government would cause wide publicity to be given of the event in order to give persons temporarily within the area at the time of exposure an opportunity to present themselves and substantiating facts for investigation and testing. The government would also have power to control the movements of property for the purpose of preventing an enlargement of the area of irradiation. It is only in case of major accidents and wide exposures that this would become a massive undertaking, but such an exposure would present a massive undertaking regardless of by whom it was done, and the Federal Government, operating for the country as a whole, is the only one who could have constantly available the quantity and type of expert personnel and other resources that would be required to expeditiously conduct the sort of investigation that would be required. Upon the completion of its investigation, the Federal Government would make a permanent record with respect to each of the exposed individuals within the exposure area. In the event the investigation convinced the government that those causing the irradiation were at fault but only then it would bring action against them, making available to them for cross checking the methods of investigation employed and the results obtained, and would seek recovery from them for the increased number of cases of the various types of non-specific, statistically related diseases that would be expected to result from the over-exposure. A formula would have to be statutorily established for determining the average amount of damage to be suffered by each person making up the total number of increased cases. The government would be permitted to have any objective less than total recovery from the defendant or defendants as in its judgment, based upon all the facts and circumstances, would be equitable in the individual situation.

Thereafter, any member of the exposed group, upon establishing that he had incurred any one of the statistically related diseases or other adverse effects and the damages resulting therefrom, would be paid by the government the damages so incurred. If, operating through administrative channels, plaintiff was unable to establish this fact to the satisfaction of the government, he would be allowed to sue in a district court of the United States to determine such issues. Plaintiffs would have no difficulties prosecuting this type of suit under the normal and customary contingency fee arrangements.

It is apparent from the foregoing that the government would pay the damages for all natural incidence cases among the exposed group as well as some of those caused by the defendants' overexposure of the population group. The question naturally arises: should the government do so? I think it should, unless we are to say that much of the cost of this socially desirable product is to be paid for in the form of personal injuries by those on whom random chance causes it to fall. If the peaceful use of radioactive materials becomes commonplace and injuries frequent, we have only a limited number of alternatives. One is to try to handle them by traditional common law concepts and procedures. Enough has been said to show the impracticability of that method.

A second alternative would be something along the lines of a private contingency fund such as that proposed by Professor Estep. But, as I understand it, his proposal presents insuperable problems. Professor Estep recognized the lack of inducement that would exist for plaintiffs to prosecute the first phase of his proposed two phase litigation process. He concluded that "most attorneys for exposed persons would go uncompensated".[6] That of course, attorneys would not willingly do. He concluded that "the only feasible solution under present practices is to have radiation injuries specialists who handle enough claims to make it very economical to try the plaintiffs cases and to have enough cases for each lawyer so that he will get a reasonable fee from such cases as a whole".[7] That, I cannot see as a solution. When we have a number of people, anyone of whom has only an infinitesimal chance of recovery, and where much of the proof to establish each individual's chance of recovery has to be personal to him, I can see no way by which a mass handling of cases, even by specialists, could be made economically attractive.

The third alternative would be something along the general lines which I propose. The many unique features of radiation injuries justify giving them this substantially different treatment.

The proposal here made would eliminate most of the unique problems of radiation injuries stemming from multiple sources except those of persons who might be injured by the intentional exposures above mentioned. With those exposures being intentional, or at least negligent, and with a record of prior significant exposures being available, it would seem that at least the last person causing the exposure would be liable unless justification could be shown for producing the increased hazard. It is a question of policy whether these cases would be left to litigation by common law methods or whether they would be included among those for which the government would make payment and seek reimbursement from the culpable actor. I would suggest that, until experience indicated a necessity for a different approach, these cases be left to common law methods of litigation.

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[6] Id. at 107

[7] Id. at 107-8

DISCUSSION

DEAN NEIBEL: We have had a presentation of one solution to the problem of radiation injuries; namely, the insurance solution. That is obviously limited to the major incidents. We have now had the discussion by Dean White of facts that must give great comfort to defense counsel as they think about the difficulties of maintaining a suit on the part of the plaintiff.

And then, we have had a proposal from Dean White that is a way to remedy that situation. At this point, I am sure you have some questions for our speakers, and the arrangers of the conference have very thoughtfully provided for a 15-minute question period. So, at this point, let us entertain questions from the audience.

DR. REYNOLD BROWN: I think the scientific community would endorse Professor White's proposal based upon his assumption that the observed incidence of disease exceeded the incidence occurring naturally, and the indemnification of those in excess of the induced naturally occurring incidence would be in order. I think we would endorse any proposal to accomplish this. But, I'd like Professor White to expound on the situation where the observed group has an observed incidence of leukemia that is less than the natural incidence of leukemia in the general population. This is actually the experience of the Atomic Energy Commission. I would ask you how you would indemnify that group within that set of parameters.

DEAN A. A. WHITE: I am at kind of a scientific disadvantage. I think that a certain number or certain amount of imperfection is going to exist in any approach to a problem. You simply take the approach you take because, on balance, you decide that it's the best of the available approaches.

I would say, that until it became statistically determined, or scientifically determined, that none of those leukemia victims who had this exposure had developed the disease because of the radiation; I would continue to pay them.

DR. BROWN: Using the attorney's talk, I don't think you're being responsive to my question.

DEAN WHITE: Well, maybe I'm not responding because I don't understand your question. But, well, let's take leukemia. Let's get a situation where maybe 107 people out of 100,000 would have leukemia as a natural occurrence.

Now, I understand you are saying that in certain exposed groups less than 107 per 100,000 have leukemia.

DR. BROWN: Well, let me make it very specific. The history is that radiologists experience an increase in the incidence of leukemia over that which would be naturally expected, regardless of how you analyze the group. I think the scientific community would endorse the indemnification of every radiologist who developed leukemia, regardless of the nature of the history of exposure or documentation of exposure, in order to be completely fair, to indemnify those who may be radiation-induced.

But, given the experience of a second group, however identified, which following the same kind of investigation shows a total incidence less than the naturally expected calculated incidence, would you then propose the same system of indemnification that you include in your proposal?

DEAN WHITE: I thought I understood your question and I intended to answer it. It's just a difficulty of communication.

And again, to make sure that I am getting across, we have 100,000 people exposed, but it turns out that instead of 107 having leukemia, 89 have leukemia. I'd pay them, unless it later became an established and accepted fact that the irradiation actually reduced the rate of incidence.

I don't think I would say that one situation of reduced incidence would be enough to establish it. But, certainly, I think you could have situations where less than the natural incidence of cases arose and yet some of those cases in the group would still be caused by radiation. So until the causal relationship was disproved, I'd pay them.

DR. BROWN: If I'm interpreting what you're saying, rather than talk about leukemia, we might talk about life-shortening effects and say, "the average group presently will live to the age of 67, so if we have a radiation worker who dies at 64, you would suggest we pay him also."

DEAN WHITE: Yes. It would be true of any of the irradiation-associated non-specific injuries.

MR. SELBY: Only if he was exposed.

DEAN WHITE: That's right. Not unless he was exposed.

MR. SELBY: And unless the permissible limits were exceeded? But, the limits that we are talking about and working together on are not set with the idea that if we exceed them slightly, we are going to do genetic damage to individuals. That's the wrong concept.

If you were setting some extremely high limit--not a limit that we are exposing our workers to occupationally--perhaps this might be true. But, if you are talking about limits that have been set by the National Council for Radiation Protection, then, I think it's the wrong concept.

DEAN WHITE: Well, as you may recall, I said above some established limit. I didn't purport to set the limit myself.

I think, probably, you would not set it so that there would be a one-ten thousandth of one per cent chance of some adverse effect. I didn't have in mind doing that.

If you note, I said that it would be set at a level so high thatyou wouldn't even report most diagnostic and some therapeutic use. I think you'd have to keep it in some sort of realistic, manageable proportion. But, I'm saying this, simply because no one, insofar as I know, has come up with an idea--and I can't come up with an idea which will result in a fair chance of compensation. I'll just use a set of figures here that we have talked about. If the exposure doubles the chances of leukemia and out of this 100,000 an additional 107 eventually have it from the doubling dose--that would not be a dosage high enough that would likely cause any immediately demonstrable effects.

At the time it happened, you probably couldn't see the chance of recovering more than nominal damages. So, what's the incentive? You don't bring the action. The changes may become manifest in five, ten, 15 or 20 years--well past the outside limit. So unless we change I think we are going to have to write off as casualties of the nuclear age a substantial number of persons who die from radiation.

FROM THE FLOOR: Just as a matter of public policy, I would like to arrange some method of compensating people whose exposure--whether occupational radiation or not--results in physical damage. I think your program might lend itself to that simply by being in existence. But, it would be difficult to justify this on a scientific basis. Perhaps the better thing to do is simply say, "We'll pay people whom we categorize as radiation workers who develop certain diseases in those industries that demonstrate increased incidence of these related diseases." You would then avoid all litigation except for purposes of proving that a radiation worker has been out of work a substantial length of time and demonstrates a related disease. Even if science doesn't back it up, you haven't lost anything at all.

DEAN WHITE: That gets pretty close to what I'm saying.

DR. WEBSTER: What you said about leukemia is very fine. I would support that general context because it is rather a rare disease and because there are signs that there would be a substantial increase in the incidence due to radiation. But, suppose you then extend it to all malignancies. Then, you might find that one-third of the people employed in radiation are dying with a cancer of some form and these other types of cancer would not be associated with their employment. Chance of causation might be really quite remote. Supposing you apply the leukemia figure of two per million per year to all of cancer, which is what people are saying. That, compared with the normal incidence, is very small. So, you would be compensating an awful lot of people whose disease was totally unrelated to radiation.

DEAN WHITE: I think that would be affected some by what exposure level you came up with.

I would agree that the great number of people who die of cancer are not radiation victims. Exposure levels entitling one to compensation would have to be such that you would reduce the size of the group receiving compensation. That would mean there would be some out-sider, no doubt, who would die of radiation-induced cancer, who just wouldn't be paid. I don't know of any perfect way to get at it.

MR. KALMYKOW: I was wondering, Dean White, exactly what situations you had in mind. I gathered from your remarks that it seemed to be a type of tort liability situation where there was a third party liability in the case. Probably a sudden incident; is that the type of thing you had in mind.

DEAN WHITE: That was mostly in my mind. And I don't know whether I said it in the beginning or not. I was talking about the common law situation as it occurs--as distinguished from Workmen's Compensation principle without any employer-employee relationship being necessary. And I'll admit there would be a lot of problems in meshing this into a Workmen's Compensation set-up.

MR. KALMYKOW: Just to clarify the situation a little bit. I was wondering if there could arise an incident where there is a question of who was liable for obvious damage such as an explosion or whatever.

DEAN WHITE: Yes, sir.

MR. KALMYKOW: Now, in a situation where there is a continuing exposure, let's say, a radiation exposure for a physical therapy set-up, there would be no question of whose negligence was involved. The only issue would be a causal relationship, and that's the thing we were discussing yesterday. And I think there, the only issue is where do you draw the line. I think that the question of who is liable would not be involved so that there wouldn't be a need for these detailed questions or how the accident happened and so forth.

The question would be that of a causal relationship. I take it you do judge that in this case if certain limits are exceeded, whatever the permissible limits might be, there'd be automatic liability for any of these certain diseases.

Now, I think this is the simple and logical conclusion and I think we're rapidly approaching that day. But, I just wanted to clarify that this is a limited situation where it might be applicable.

DEAN WHITE: Yes.

DR. NORMAN TELLES: I agree with Dr. Webster's comment. I would point out, though, that probably we would want to indemnify only those individuals whose cancer was of a type known to be induced by radiation. It should be established that this type of cancer could be induced by radiation. In other words, not all cancers thus far are connected in causation to radiation. I think it should be necessary to show that a causal relationship between tumors of this type and radiation had been scientifically established.

As you pointed out, after an exposure there are difficulties of establishing medically an injury of some sort which might in later years manifest itself in the development of some sort of cancer or leukemia.

Now, are relationships between genetic alteration and diseases going to be established in the future which are not now very well established, say, for leukemia or other kinds of cancers?

Consider the result from radiation exposure in humans at low levels. I think Dr. Bushong yesterday referred to the fact that you might detect chromosome alteration with as little as five rads exposure to an individual.

Perhaps we might have chromosome analysis done shortly after the suspected exposure and have that be admissible in court as a kind of supporting evidence for an individual making a claim of injury, recognizing the current limitation in our knowledge of chromosome alteration?

And then, I have another question: How would you compensate that individual who, following the single or multiple exposure, manifests not one, but more than one kind of injury, and not necessarily all at the same time? This is a conceivable problem.

DEAN WHITE: Well, let's talk just a little about that last one and then, you may have to remind me what your first one is.

But, that is a major problem. It's one of the things I didn't touch. You've got such a multitudinous list of cases involving the statutes of limitations and a lot of other things, that it's awfully hard to make any statement that is very definite. But, that is certainly in the jurisdictional address to your statute of limitations. Suppose that the statute of limitations runs from the time your bodily integrity has been invaded--and a few States say that. All right. You have been exposed. Your bodily integrity has been invaded. You sue. What damages can you get at that moment? That is, assuming the exposure is not one of the ones that leads to immediate and serious consequences. What damage can you get? You get nominal damages.

Say you get an injury five or ten years later. You have cancer or some other ailment that manifests itself and you want to sue. You are met with what we call the doctrine of res judicata. Now, maybe that doctrine can be revised and relaxed. But, normally, you have only one bite at the apple, as we say. You not only adjudicate what you actually knew about; you adjudicate all those things that should have been involved in the litigation. Now, maybe somebody would say, and some court may be bold enough to say, that the doctrine of res judicata won't apply and we will let them bite on this apple as each injury manifests itself.

Now, back to the chromosomal changes; certainly, I don't think there is any doubt that would be good evidence, based on such superficial scientific knowledge as I have of the subject. But, what would motivate a person to have that sort of investigation made?

Now, at the same time you ought to establish who irradiated you. Sometimes that will be known and sometimes it won't. And you've got to establish the fact of the irradiation. And that, unless somebody would just admit it, you may have to do in court. Unless people just come in and voluntarily say, "Well, now, that measure of exposure was given to this man by us." So, you see, at the outset, you've got some proof problems.

Who's going to be interested in these cases? Suppose you've got one case in 10,000 with the exposure you suspect and suppose it costs you $1,000 to make this preliminary proof and establish it. What is that? You'd have to have a possible ultimate recovery of $1,000,000 to make it a good gamble. Is that it? So, you, see, it's a threshold proof that presents a tremendous problem.

DR. BUSHONG: I think we are lending too much weight to chromosome analysis. Let me reiterate and reinforce something that I covered yesterday in my review:

If we take a mass of biological material and irradiate it, we can also take these cells and culture them in a certain way and measure very precisely the chromosome damage. If that mass of biological material were a human being, we cannot make any statement whatsoever regarding the relationship between the chromosome damage and any latent physiological effect. To my knowledge no one has even suggested the relationship, because there's no evidence to support any relationship between chromosome damage and latent physiological effect.

Further, we don't even today have an acceptable relationship between chromosome damage and cell death, although, on the basis of some work in our laboratory, we have attempted to establish this relationship. It is a one-to-one relationship between chromosome damage and cell death. But, this still is not totally acceptable.

PROFESSOR COX: I just want to make one comment. I think that Dr. Telles was worrying about our problem of legal proof. I'm not sure whether or not you could scientifically establish the historical data behind some chromosome change, but when introducing this type of evidence, it might be claimed that this chromosome change could have existed before the radiation, and this would be a problem so far as introducing the data.

If you could establish that this chromosome change had developed within X number of hours following radiation exposure, it might be important in establishing that it did relate to the injury. But, that is still a problem.

PROBLEMS OF LEGAL PROOF IN RADIATION CASES

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We are all familiar with Winston Churchill's famous aphorism to the effect that the English and American people are divided by a common language. The profound truth in this aphorism is equally applicable to conversations between doctors and lawyers. Although our respective professions have their particular vocabulary (with its combination of precision and mystique), we also use words in common. Like the Englishman who misunderstands the American, the doctor and the lawyer sometimes misunderstand each other when they assume that words used in common have a common meaning.

All of this is relevant to legal proof in radiation cases. I intend to focus my attention especially on the word "causation" as it arises in the context of a claim for damages arising from physical injuries or diseases allegedly caused by exposure to ionizing radiation. Whether the case is litigated in the context of workmen's compensation laws where problems of fault are irrelevant, or in the context of a negligence claim, the plaintiff is faced with the necessity of convincing the tribunal that his physical condition was in fact caused by the exposure to the radiation. The inquiry which the court is making would appear on the surface to be identical with the kind of inquiry that a doctor makes when he examines a patient, discovers a pathological condition, and seeks to determine the cause as a step in prescribing appropriate treatment. Each social agent--the court and the physician--must confront the problem of causation.

And so it is that when the physician comes into the courtroom and is asked to testify concerning the cause of the plaintiff's pathology, it would appear that the occasion requires nothing more than a translation of the physician's finding on causation into terms understandable by the court. The entire discussion is carried forward under the single rubric of causation. This I suggest, is a specific example of an important instance in which the use of common language serves to create a dangerous confusion. I shall attempt to show that the medical profession's notion of causation, while of interest to a court of law, should not be controlling when one explores the real nature of the legal notion of causation.

This issue may be of no practical importance if we are dealing with an injury which so obviously resulted from an exposure to ionizing radiation that there is no room to doubt the nexus between the exposure and the pathology. If X-ray therapy produces an area of burned tissue beyond the intended target area of the body, there can be no room for doubt in anybody's lexicon that the exposure to the source "caused" the burning. Other legal questions will be the critical ones in the litigation, especially the question of negligence. If, however, the alleged effect of the radiation exposure is delayed, the problem of causation becomes much more difficult. If, further, the alleged effect of the radiation exposure is "an ordinary disease of the body," such as leukemia, the problem of causation becomes extremely perplexing. It is in these more difficult cases that a close analysis of medical notions and legal notions reveals that we are, indeed, two professions divided by a common language.

My interest in this matter is not merely academic. Too often our courts have accepted medical testimony concerning causation when the testimony is addressed to a concept of causation but is inappropriate for application in determining legal liability. With this audience it may be presumptuous of me to purport to explain the medical idea of causation, but I suggest that it is directed towards what is more properly called "etiology". The medical inquiry into etiology is an attempt to discover the biological processes by which a particular pathological situation developed. The medical man is never certain that he knows the cause of a disease until he knows exactly how the biochemical processes brought it about. In the case of a number of the ordinary diseases of life, the etiology even now remains unknown. As a consequence, men of medicine refrain from passing judgment on causation.

Perhaps, I have put this too strongly, for it is very common to find negative judgments on causation in situations where the etiology has not yet been determined. For instance, we have innumerable cases in which expert medical testimony declared in the courtroom that cancer cannot be caused by trauma. This testimony comes from men who are unable to explain what does cause cancer, but the devastating effect of their testimony on a claimant's suit is obvious. In a few instances, courts have made awards to such claimants despite these medical disavowals of causal nexus. How can a court of law support a finding that cancer has been caused by trauma when the medical testimony indicates that we do not know how cancers originate? The answer to this riddle lies in the fact that the medical idea of causation is not and should not be the same as the legal idea.

When a court of law is attempting to determine the causation of a plaintiff's pathological condition, the court is faced not with the question of scientific etiology, but with a policy problem, namely, whether under all the circumstances it is fair to shift the economic consequences of this pathological condition from the plaintiff to the defendant. This inquiry into causation in the courtroom is a reflection of social purposes and not merely of biochemical knowledge. Particularly in the context of a workmen's compensation case, sound social policy may dictate that it is both proper and fair to require an employer to compensate an employee for the loss of earning power consequent upon the development of a disease, even though the present state of medical knowledge cannot tell us with firm assurance that the disease developed through biological processes set in motion by an industrial exposure.

Let us take for example an employee who has been repeatedly exposed to phenol. After a number of years of this employment, he develops aplastic anemia. Medical experts tell us that there can be a "relationship" between exposure to phenol and the onset of aplastic anemia. We also know, however, that most persons who develop aplastic anemia have no history of exposure to phenol. Furthermore, most persons exposed to phenol never develop aplastic anemia. Medical knowledge has not risen to the level of a satisfactory and complete explanation of the etiology of this blood disorder. When the employee brings a claim for workmen's compensation, he is required to show that his condition was "caused" by his employment. In the statutes this is most commonly expressed in terms of a requirement of proof that the disease arose "out of and in the course of the employment." Should his claim be denied and the economic loss from his condition remain solely on the employee and his family, or should it be shifted to the employer? The conscientious medical expert may declare that he is unable to state whether the employment "caused" the disease. I suggest, however, that sound social policy and a decent sense of justice require that in this case the employee be compensated.

The thesis that is being presented is a modest one. If there is no medical basis for a rational belief that there is a relationship between the job and the disease, no one would suggest that the employer should pay. On the other hand, medical evidence indicating the distinct possibility of a relationship between the job and the disease, while insufficient to support finding of causation in the medical sense, may warrant a finding of causation in the legal sense. The point, of course, is that the problem of the courts in these areas is not to settle medical questions, but to determine the allocation of losses in a manner consistent with sound social policy and a decent concern for justice to the parties.

As a matter of fact, doctors, too, use causation in special senses, depending upon the context. Of course, medical men prefer to base conclusions about causation on a compelling statistical study of the relationship between a suspected causative factor and the disease. This has been done in the radiation field in the case of lung cancer among uranium miners. These longitudinal studies, using an exposed population group and one or more control groups, are a principal device for testing causal theories involving human pathology. Unfortunately, the practical possibility of conducting such a study exists only in a limited number of situations. It is also important to note that a longitudinal study yields information concerning probabilities of causal nexus in a population, but the legal problem always is to determine causal nexus in each individual case. In any event, the unspoken medical assumption is that causation is a pure question of scientific fact.

Medical opinions concerning causal connections, however, are not always so innocent of policy implications. An obvious example is found in the relative alacrity with which physicians assert a causal nexus between new drugs and pathological symptoms in patients to whom the drugs are administered. In this context the purpose of determining causation is to aid in making informed judgments concerning the prudence of prescribing the new drug for a patient. The benefit hoped for must be weighed against the risks. Doctors do not wait for longitudinal studies before expressing opinions in this situation, nor do they hesitate to declare that even "nonspecific" pathological conditions have a specific cause in particular cases.

The literature of medicine is replete with examples of this kind of judgment concerning causation. British doctors have reported two fatal cases of aplastic anemia "believed to be due to" the administration of a drug called Tegretol. They reached this conclusion although the two cases were the only instances of aplastic anemia known to have occurred among more than 17,500 patients to whom the drug had been administered. Furthermore, the researchers admitted: "If there is a causal relationship between Tegretol and aplastic anemia in our two cases, it is not possible to state whether the mechanism is one of drug idiosyncracy or of slow toxicity." The drug was known to have a chemical kinship to drugs which were "known" to cause (through infrequently) blood dyscrasia, but in one of the two cases the record revealed other possible explanations for the onset of the anemia. The doctors set forth an opinion incriminating Tegretol although they declared: "The evidence which incriminates a drug as a cause of marrow aplasia is always circumstantial. New drugs tend to be used in patients already treated with standard therapy and this obscures causal relationship." It is of interest to note a third case of aplastic anemia (nonfatal) following administration of Tegretol has more recently been reported.

One of the most interesting examples of medical judgments concerning causation is found in the famous report on "Smoking and Health." Nowhere in the report is the idea of causation defined, although we are told that various meanings were debated at a number of meetings. The reader is left with a vague but realistic warning:

> "It is recognized that often the coexistence of several factors is required for the occurrence of a disease, and that one of the factors may play a determinant role, i.e., without it the other factors (as genetic susceptibility) are impotent...The word "cause" is the one in general usage in connection with matters considered in this study, and it is capable of conveying the notion of a significant, effectual, relationship between an agent and an associated disorder or disease in the host.
>
> It should be said at once, however, that no member of this Committee used the word "cause" in an absolute sense in the area of this study. Although various disciplines and fields of scientific knowledge were represented among the membership, all members shared a common conception of the multiple etiology of biological processes. No member was so naive as to insist upon monoetiology in pathological processes or in vital phenomena. All were thoroughly aware of the fact that there are series of events in occurrences and developments in these fields, and that the end results are the net effect of many actions and counteractions."

With a potentially serious impact on a large industry and its advertising media, the report on "Smoking and Health" was certain to be examined critically, and great care in finding causation was to be expected. At least three kinds of conclusions concerning causal nexus are discernible in the conclusions of the Committee. It is unequivocally declared: "Cigarette smoking is causally related to lung cancer in men; the magnitude of the effect of cigarette smoking far outweighs all other factors." More guardedly the report states: "Cigarette smoking is a significant factor in the causation of laryngeal cancer in the male." An even more tentative conclusion declares: "The evidence on the tobacco-esophageal cancer relationship supports the belief that an association exists. However, the data are not adequate to decide whether the relationship is causal."

At what point was the Committee prepared to find a causal connection? The only unequivocal finding was based upon evidence that the risk of lung cancer among male smokers was from nine to ten times as great as among male nonsmokers. The

Committee was reluctant to label the "association" between smoking and coronary artery disease a causal one, despite a finding that this disease was the chief cause of excess deaths among smokers. One cannot read the report without sensing that judgments concerning causation reflect a rich and mysterious mixture of science and policy, the context within which the judgment is being made and the purposes for which it is being made playing a major role.

In radiation cases, however, most medical testimony continues to be expressed in terms of the theories of etiology without references to the policy framework of compensation laws. A few examples will suffice. One case was disposed of when an expert gave uncontradicted testimony that "leukemia is a disease of unknown cause." In another, involving cerebral atrophy, there was medical testimony that this condition is "of unknown etiology," and an appeal was denied on the basis of an argument that the issue "is one which lies essentially within the realm of medical knowledge." Yet another doctor testified that leukemia's causation is a "theoretical question," one to be decided by the researchers. None of these statements addresses itself to the causation issue as it should be confronted in compensation cases. By purporting to decide radiation injury claims purely on a theory of etiology, neither the medical nor the legal professions are displaying an awareness of the extent to which policy notions color their ideas of causation. Cause-in-fact is not a neutral principle. By allowing the medical view to dictate the result of radiation claims, the legal process is not only abdicating its responsibility to apply the policy of the workmen's compensation statutes, but is also allowing the unexpressed policy judgments of the medical expert witness to influence the result.

Surely, at this point some of you must be asking yourselves how far I propose to go in assessing liability for delayed, nonspecific pathology alleged to be ascribable to earlier exposure to ionizing radiation. I can give only a general answer to this question. Even this answer must be a divided one, distinguishing between radiation exposures on the job and exposures in a context in which there is no liability unless there is negligence, as in the ordinary doctor-patient relationship.

With respect to the first class of cases, I would be prepared to go far in assessing liability. This class includes not only occupational exposure, but also medical exposures in the course of diagnosis or treatment of occupational injuries or diseases. If the evidence showed that there had been a potentially damaging exposure, and the pathology was of a type to which the exposure could have made a material contribution, the tribunal should be free to charge the employer (really its insurer) for the loss of earning power. Nothing less than this would be consistent with the policy and purpose of our workmen's compensation laws, which typically include a provision that they should be liberally interpreted to protect the employee. We must also keep in mind that the employers have been immunized against common law liability in exchange for their workmen's compensation liability. Furthermore, the compensation laws cover loss of earning power and give nothing for pain and suffering, loss of life expectancy (at least as to the years in excess of normal working life), or genetic damage. Who can view with equanimity and a sense that justice has been done the negative disposal of the early cases involving lung cancer in the uranium miners of Nevada? They had the misfortune of dying before the longitudinal studies were completed. Indeed, their deaths contributed to these studies. It had already been known for a generation that uranium ores had some carcinogenic quality. For men of medicine to reserve judgment on causation may have been right and proper for courts of law to deny compensation was palpably unjust.

The second class of cases is that in which negligence must be shown. In this category there is no public policy of general acceptance which supports preference for the plaintiff. But even here, if the evidence of negligence is clear, and the causal relationship--though not clearly established--is distinctly possible, sound judgment requires that the plaintiff receives a favorable judgment. One way of putting the issue is to ask who should bear the burden of our semi-ignorance, the innocent plaintiff who had been hurt, or the negligent defendants whose acts or omissions plausibly contributed substantially to the plaintiff's pathology? Again, it must be emphasized that this is not to suggest an award or judgment in favor of a claimant who has not shown, realistically and scientifically, the potential causative power of the forces for which the defendant was responsible.

It would be pleasant if one could report that the courts agree with my view. For the most part, they do not. Two cases stand out as being consistent with this approach. In one of these cases, the New York Courts made an award to an employee who died with acute myeloblastic leukemia. The employee was a theoretical physicist who worked adjacent to a laboratory where radio-active materials were stored. From time to time he used equipment which was separated from the hot laboratory by a wall of masonite. Measurements showed that an ion-exchange column sent through the wall from six to ten mr per hour. There was also in the area a 201 millicurie cobalt 60 source, and another similar source of unspecified size. The record of the case makes it impossible to determine with any degree of accuracy the actual exposure of the employee. The court supported the award by emphasizing the insufficiency of our scientific knowledge concerning safe dosage and also the possibility of individual susceptibility different from average experience.

The other case was in Maryland and involved an X-ray technician who had an unmeasured exposure during seven of the eleven years prior to developing the symptoms. Without the protection of shielding, he took chest X-rays numbering as high as fifty per week. When he developed chronic leucocytosis, extensive efforts were made to determine the cause. No possibility appeared except the X-ray exposure. Although the medical board declared that causation had not been proved completely, they awarded compensation because the exposure could have produced the blood changes and no possible explanation was available. These two cases strike me as reflecting a practical, realistic, and fair approach to the problem of causation, at least in the context of a workmen's compensation case.

Other courts and agencies have used an escape-hatch which is of doubtful acceptability. By finding that the claimant who has been exposed to radiation suffers fron an anxiety neurosis, it becomes possible to award compensation without making a ruling on the difficult question of whether the radiation exposure had a causal relationship to the pathological symptoms. A number of cases in New Jersey have been decided in this fashion. This easy method of circumventing difficult issues does not appear to have much to recommend it.

There are other problems, some perhaps as fundamental in legal importance as that of causation, which deserve development, but time prohibits. Brief mention of two of these is essential. There has already been extensive discussion during this conference concerning radiation measurements. At this point, I wish only to indicate that in the courtroom evidence which is presented in mathematical terms tends to receive a degree of respect in excess of what the underlying facts would warrant. Radiation exposure records are often treated as if they are absolutely reliable indications of the full extent of a person's exposure. The complications underlying the technology of radiation monitoring tend to be overlooked, and the records are given the same credence that would be given to a report of the patient's blood pressure. This puts a claimant in a very difficult position and sometimes makes proof of his case impossible. The answer to this problem lies not only in the direction of improved radiation measurement, but also in a more candid presentation of radiation exposure records and their limitations so that a tribunal hearing a case will not be unduly swayed by the mathematical quality of the evidence.

In similar fashion, safety standards sometimes receive unrealistic courtroom treatment. In a substantial number of cases a party who claims injury or disease from radiation exposure has had his case absolutely defeated when it was shown that his recorded exposure was not in excess of maximum allowable exposure. It hardly need be said that safety standards have been set not in terms of absolute protection, but in terms of practical judgment. Total protection against harm from radiation would require a health standard of zero exposure. The standards are set through balancing of the risks with a practical eye to the economic and political factors in favor of use of sources of ionizing radiation. Since the standards were never intended as indications of the level of absolute safety, they should not be so used in the courtrooms.

If time permitted, something should be said about industry's attitudes. It is characteristic of any professional group to be defensive when it is alleged that the activities of its members have caused harm to other persons This defensiveness is particularly strong in new industries which have been challenged as posing potentially fearsome hazards to human biology. The prevelance of this attitude among persons who work with radiation has tended to make expert testimony unequally available between plaintiff and defendant when claims for radiation damage are litigated. The problem is not unique to radiation cases, but is especially serious in these instances. One would hope that as the use of ionizing radiation in society becomes more extensive and familiar, the practioners of these complicated arts and sciences will come to recognize that a charge that harm has been done is not a group indictment and, indeed, may not involve any fault or negligence at all. In appropriate cases expert testimony should be available to claimants whose allegations appear to have a basis in fact. Up to the present time, the record of adjudication in radiation cases reflects the ready availability of experts for the defense while the claimant is left to rely upon the testimony of general practioners of medicine who can claim no high qualifications in the radiation field. In this unequal battle, the claimant has an extremely limited chance of success.

Finally, it must be recognized that in the discussions of all these issues we are talking about merely one branch of the vital national question of health care for the American public and social responsibility for major personal physical catastrophes. In the absence of a national health and compensation policy, pressures constantly grow to expand each partial policy beyond its logical limits. The law of negligence, of product liability, and of workmen's compensation are limited programs of legal protection against the economic consequences of accident and disease. The task of our courts is to apply these laws in the growing field of radiation hazards in a manner consistent with the underlying policies. It is to this end that I have urged a new look at the problem of causation in radiation cases.

THE DOCTRINE OF RES IPSA LOQUITUR IN RADIATION INJURIES

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I. - THE HISTORY

To understand what, if any, relationship or usages the doctrine of res ipa loquitur might have in radiation cases, it is well that we review in the beginning what the doctrine of res ipsa loquitur is all about, and more importantly, what it is not about.

In 1863, Baron Pollock wrote an opinion about a negligence case, where a barrel of flour had rolled out of an upper story warehouse window and had fallen on a pedestrian. He occasioned to use the Latin phrase, "Res Ipsa Loquitur," in fact relating that certainly negligence must have existed in this case for the incident to have occurred. Thus, in the case of Byrne vs. Boadle, 2 H & C 722, 159 Eng. Rep. 299 (1863), there came into being in Anglo-American law the phrase with which we are here concerned.

"The thing speaks for itself" is one of those axioms which, because of its Latin appeal and because of its more apparent than real ease of understanding, has lived on in the law and is a very important part of the law of negligence. Certainly, in that particular instance, there can be no quarrel with the logic of Baron Pollock's analysis.

Later, in the case of Scott vs. The London and Catherine Docks Company, 159 Eng. Rep. 665 (1865), there was set out for the first time an analysis of the doctrine of res ipsa loquitur. In that case, the requirements were:

1. Negligence must ordinarily be proved, but
2. Where the instrument causing the damage is shown to be under the management of the Defendant, and
3. The accident is such that in the ordinary course of things does not happen if those that have the management of the instrument use proper care, then,
4. In the absence of explanation by the Defendant there is a reasonable inference that the accident arose from the want of care (negligence).

This decision came about in a case involving six bags of sugar which fell from an unloading sling onto a passerby; and again, like the barrel of flour case, hardly seems open to dispute. Take note here, in the first definition of the doctrine, the requirement was that the instrument causing the damage be established before the doctrine became applicable. Thus, in its very inception, it was recognized that there must have been established, already, causation from the act complained of to the injuries alleged before the doctrine would be applicable.

It has always been elementary in the Anglo-American tort law that one seeking to recover damages inflicted by the alleged acts of another must prove that these acts were negligent by a preponderance of the evidence. Missouri Pacific Railroad vs. Porter, 73 Tex. 304; 11 S.W. 324 (1889). Negligence will not ordinarily be presumed. International and Great Northern Rwy. vs. Wilson, 129 S.W. 849 (1910). Certainly, the mere account of an injury or the happening of an accident ordinarily is no evidence of negligence. McCrea vs. Galveston H. & S.A. Rwy., 89 Tex. 168; 34 S.W. 95 (1896).

As stated by Mr. Morris, in his article "Res Ipsa Loquitur in Texas," 26 T.L.R. 257:

> "Res ipsa loquitur, whatever its elements, is aimed at the establishment of negligence of the Defendant. It has nothing to do with duty or causation, and its application does not mean automatic liability. In a lawsuit, it has to do with only one issue, the negligence issue. All that is said about res ipsa loquitur must be considered in relation to that issue."

In Wigmore Evidence, First Ed. (1905), Sec. 2509, the Dean of modern evidence defines the doctrine of res ipsa loquitur as follows:

1. The event must be of a kind which ordinarily does not occur in the absence of someone's negligence.
2. It must be caused by an agency or instrumentality within the exclusive control of the Defendant.
3. It must not be due to any voluntary action or contribution on the part of the Plaintiff.

Prosser, in his "Handbook on the Law of Torts," 3rd Ed. 1964, Sec. 39, page 281, reveals that Wigmore's definition of res ipsa loquitur has been the source of that doctrine's universal recognition by American courts. Jurisdictions recognizing this definition of res ipsa loquitur include the following:

United States: Jesionowski vs. Boston & Maine R.R., 67 Sup. Ct. 401; 329 U.S. 452; 91 L. Ed. 416; 169 A.L.R. 947

Alabama: *Reichhert Milling vs. George*, 230 Ala. 3; 162 So. 393

Alaska: *Crawford Vs. Rodgers*, 406 Pac. 2d 189

Arizona: *Tiller vs. von Pohle*, 72 Ariz. 11; 230 Pac. 2d 213

Arkansas: *Gray vs. McLaughlin*, 207 Ark. 191; 179 S.W.2d 686

California: *Zentz vs. Coca Cola Bottling of Fresno*, 39 Ca. 2d 436; 247 Pac. 2d 344

Colorado: *Yellow Cab Co. vs. Hodgson*, 96 Colo. 356; 14 Pac2d 1081

Connecticut: *Briganti vs. Connecticut Co.*, 119 Conn. 316; 175 Atl. 679

Florida: *West Coast Hosp. Assn. vs. Webb*, 52 So.2d 803

Georgia: *Harrison vs. S.E. Fair Assoc.*, 104 Ga. App. 596, 122 S.E.2d 330

Hawaii: *Ciacci vs. Woolley*, 33 Haw. 247

Idaho: *Whitt vs. Jarnagin*, 91 Idaho 181; 418 Pac 2d 278

Illinois: *Metz vs. Central Ill. Elec. & Gas*, 32 Ill.2d 446, 207 N.E.2d 305

Indiana: *N.Y. & C. St. L. R. vs. Henderson*, 237 Ind. 456; 146 N.E.2d 531

Iowa: *Brown vs. Sioux Bldg.*, 248 Iowa 948; 93 N.W.2d 471

Kansas: *Blue Stem Feed Yards, Inc. vs. Croft*, 191 Kan. 605; 383 Pac.2d 540

Kentucky: *Welch vs. Cooke Chevrolet*, 314 Ky. 634; 236 S.W. 2d 690

Louisiana: *Dorman vs. T. Smith & Son*, 233 La. 29; 64 So.2d 833

Minnesota: *Fandel vs. Parish of St. John*, 225 Minn. 77; 29 N.W.2d 817

Mississippi: *Peerless Supply Co. vs. Jeter*, 218 Miss. 61; 65 So.2d 240

Maine: *Corbett vs. Curtis*, 225 A.2d 402

Missouri: Hasemeier vs. Smith, 361 S.W. 2nd 697

Nebraska: Sober vs. Smith, 179 Nebr. 74; 136 N.W. 2d 372

Nevada: Garabaldi vs. Waldren, 74 Nev. 42; 321 Pac. 2nd 248

New Hampshire: Akerly vs. R.E.A., 96 N.H. 396; 77 A2d 856

New Jersey: Burnstein vs. Metro Bottle Co., 26 N.J. 263; 139 A2d 404

New Mexico: Hisey vs. Cashway Markets, 77 N.M. 638; 426 P2d 784

New York: Serbalik vs. State, 123 N.Y.S. 2d 212; 204 Misc. 2; ;3; N.Y.S. 2d 550; 283 App. Div. 1136

North Carolina: Lea vs Carolina Power & Light, 246 N.C. 287; 98 S.E. 2d 9

North Dakota: Bergley vs. Mann, 99 N.W. 2d 849

Ohio: Weller vs Wornsteel, 129 Ohio St. 596; 196 N.E. 637

Ohlahoma: Norman vs. Greenland, 403 pac..2d 507

Oregon: Gow vs Multnonah Hotel, 191 Ore. 45; 224 Pac2d 552

Pennsylvania: O'Brien vs Gray, 121 Pa. Super. 27; 192 Atl. 746

South Dakota: Hansen vs. __________ 705 S.D. 529; 19 N.W. 2d 521

Tennessee: S.E. Aviation, Inc. vs Hurd, 209 Tenn. 639; 355 S.W. 2d 436

Texas: Roberts vs. Texas & P.R. Co., 142 Tex. 550; 180 S.W2d 330

Utah: Curby vs Bennett Glass, 99 Utah 80; 103 Pac, 2d 657

Vermont: Joey vs. Jones, 115 Vt. 174; 55 Atl.2d 181

Washington: Kind vs. City of Seattle, 50 Wash.2d 485; 312 Pac2d

West Virginia: Mecum vs. FMC Corporation, 143 W. Vs. 627; 103 S.E. 2d 897

Wisconsin: Mays vs. Milwaukee & Suburban Corp., 274 Wis. 616; 80 N.W. 2d 761

Wyoming: Carson vs. Wilson, 56 Wyo. 218; 108 Pac. 2d 260

Only Michigan, in the case of Willys Estate vs. Wolf's Estate, 345, Mich. 408; 76 N.W. 2d 52, and South Carolina, in the case of Bellamy vs. Hurdee, 129 S.E. 2d 905; 242 S.C. 71, and Wainwright vs. Thomas, 250 Fed. Supp. 963, seem not to recognize the doctrine. However, both states use the rationale behind res ipsa loquitur in the analysis and utilization of circumstantial evidence. Under what is sometimes called the Michigan Rule, where circumstantial evidence, due to its preponderance, raises itself beyond the level of speculation and conjecture, then an inference based upon it may sometimes come into being and form the factual basis for an inference of negligence based upon the circumstantial evidence.

As is readily seen, the doctrine and the rationale of res ipsa loquitur is not a tool of "causation," but an arm of the negligence law. In Bish vs Employers Liability Assurance Corp., 236 Fed.2d 62, 5th Cir. (1956), the claimant alleged to have contracted a disease from using a home permanent preparation known as "Toni." After utilizing it, the following day she developed itching of the scalp, followed by skin eruptions; later her kidneys became impaired and following a very severe illness she was diagnosed as having developed **leukemia.** In seeking to recover on a direct action against the insurance company for the manufacturer (this practice is permitted under Louisiana Law), the Plaintiffs relied on res ipsa loquitur, and prayed for damages in the amount of $195,000.00 Upon a trial verdict for the Defendant, Plaintiff appealed. The Circuit Court, in affirming the case for the Defendant on Plaintiff's point of error that res ipsa loquitur has established a basis for recovery, said:

> "The doctrine of res ipsa loquitur is not one of causation; it does not dispense with the requirement that the act or omission of the manufacturer on which liability is predicated be established as the proximate cause of Plaintiff's injury. Rotz vs Ouachita Coca Cola Bottling Co., La. App. (1936); 166 So. 151. White vs. Ameranda Petroleum Corp., La. App. 1953; 69 So. 2d 546; 65 C.J.S. Negl. Sec. 220 (8) (b); AA, P. 1011. Only when the cause is established and the manufacturer is identified with it may res ipsa loquitur be called upon to supply lack of proof as to negligence. The Court of Appeals of Louisiana has adopted this general rule thus stated:
>
> > 'Accordingly, although the responsibility of Defendant is ordinarily inferred in conformity with the statements of the rule (res ipsa loquitur), from his management or control of the injuring agency, where all the facts connected with the occurrence fail to point to the negligence of the Defendant as the proximate cause of the injury but show a state of affairs **where it** could, with equal **reasonableness** and consistency, be inferred that the accident was due to a cause or causes other than the negligent act of the De-

> fendant, as where there are several persons or causes which might have produced the injury, some of which were under the control or management of Defendant and others of which were under the control or management of the complaining party or of a third person, and the accident may have reasonably occured by reason of acts for which Defendant is not liable, the doctrine cannot be invoked. So the mere possibility that Defendant's act could have caused the damage does not warrant the application of the doctrine, and the same is true where it is, as a matter of surmise or conjecture, only that the damage was due to a cause for which Defendant is liable.'"

In General Motors Corp. vs. Muncey, 367 Fed.2d 493, 5th Cir. (1966), a pedestrian sought recovery for injuries suffered when a car leapt the curb, causing damages. In seeking to invoke the doctrine of res ipsa loquitur, under the peculiar facts of what case, the Court, in reversing and rendering for the Defendant, had this to say:

> "The fact of an accident does not prove or create a presumption of negligence. (Citing Interstate Circuit vs. Lee Normand, 5th Cir. (1938), 100 Fed.2d 160; Emmons vs. Texas & P.R.R. Co., Tex. Civ. App. 149 S.W.2d 167; Talley vs. Beaver & Hindes, 33 Tex. Civ. App. 675, 78 S.W. 23). The accelerator might have been held down by Mrs. Hudnall's foot; it might have stuck due to some external interference with normal action following the release of pressure applied by the foot; it might have been due to negligence of General Motors in so designing or assembling the accelerator or mechanism as to cause it to stick when pushed to the floorboard; there might have been some other cause for the motor racing and the wheels spinning. The Plaintiff, in an action to recover for personal injuries alleged to have been caused by a negligent act or omission of a Defendant must prove the act or omission upon which liability is predicated. If there is evidence of causation, the doctrine of res ipsa loquitur may be invoked to supply a deficiency of proof as to negligence. National Hotel Co. vs. Motley, Tex. Civ. App. 123 S.W.2d 461; Bish vs. Employers Liability Insurance Corp. 5th Ci . (1956, 236 Fed. 2d 62. Under Texas Law, the doctrine of res ipsa loquitur is not applicable on the facts of this case. (Emphasis ours)

The court went on to discuss the sufficiency of the evidence and correctly analyzed the situation where several possibilities are equally suspected, along with the claimed tortious acts or omissions:

"Although the governing substantive law is Texas law, the question as to whether the Munceys presented sufficient evidence to take their claim to the jury is a matter of Federal law. Ford Motor Co. vs McDavid, 259 Fed. 2d 261 cert. den., 358 U.S. 908, Sup. Ct. 234, 3 Lawyer's Ed. 2d 229. Where, as in the case before us, the accident may have resulted from one of several causes, for some of which the appealing Defendant was not responsible, a verdict against such Defendant is based upon speculation and conjecture and cannot stand. New York Central R.R.Co. vs. Ambrose, 280 U.S. 486; 50 Sup. Ct. 198; 74 Lawyer's Ed. 563; citing other cases."

Likewise, in the cases of Traveler's Insurance Company vs. Hulme, 213 Pac.2d 645, Kansas Sup. Ct. (1950), and Chandler vs. Anchor Serum Co., 426 Pac.2d 82, Sup. Ct. of Kansas (1967), the Kansas Supreme Court, in discussing the relationship of res ipsa loquitur to causation held that res ipsa loquitur had no application to proximate causation or to the establishment of an initial or fundamental fact bearing on causation.

These cases seem to say and the better view is that when the foundation of fact or of causation is established, then such foundation of fact may be subject to the application of res ipsa loquitur, and under proper circumstances, be inferred to be negligence. The Courts are universally agreed that in a situation where there are several possible causes, all of which are of equal stature, res ipsa loquitur cannot be utilized as an inference to elevate one possible cause above others, and establish one possibility as a fact of negligence to the exclusion of other equal possibilities. Thus, with a very shallow background of res ipsa loquitur behind us, we shall now attempt to move into the area of radiation injuries.

II. - THE PROBLEM

The problems facing any would-be claimant seeking recovery for radiation-caused injuries are not new. Regardless of those who would say that, under the present law persons damaged by radiation are substantially prohibited from making or obtaining reasonable compensation, whether in tort or under workman's compensation schemes; this writer is of the opinion that, in most instances, the difficulty encountered has been that those representing would-be claimants:

(1) Have not understood the problem
(2) Have not be conversant with radiation, and
(3) Have not changed their method of approach to meet the new causation

To others, I would say that one convinced of the relationship between a particular radiation exposure and a claimed injury, convinced though he is, may have very little foundation in fact for such conviction. All of us attempt to explain things in a simple relationship of cause and effect, not because it is true but because it is simple. When you have nothing to blame, that which is mysterious or misunderstood frequently becomes the scapegoat for everything unexplained. Witness the rise of the scapegoat "virus", blamed for everything from headaches to ingrown toenails; from sores to flu to colds -- you name it. Some persons' lawns have even become infected with the "cinch bug virus." When a person feels out of sorts, the first thing he thinks about when he cannot explain it as a hangover or something else indentifiable, calls it a "virus."

While virus these may be, human nature being what it is certainly makes it blameworthy for more than its share of ills. This phenomenen is also true about radiation.

It is recognized that all humans in the United States receive between 110 to 145 millirems of natural and background radiation every year. Yet, from personal experience in the case of Parker vs. Employers Mutual Liability of Wisconsin, 418 S.W.2d 570, (1967), writ granted, the claimant received a recorded dosage of unnatural radiation at his jobsite of 36 millirems over a period of four years. After developing lymphosarcoma in the left supraclavicular area, the claimant became convinced it was radiation-induced from that which he received on the job. I am certain that no one could convince him otherwise. Yet, he had received yearly chest x-rays and natural background radiation greatly in excess of the work-incurred radiation over the same period. Logic is faint in the face of conviction.

In radiation cases where the injuries are of a immediate, observable and predictable nature and come about as the result of radiation exposure, there is posed no more difficult problem than the ordinary case where the injury follows a traumatic incident. In these instances the ordinary problems of negligence, if applicable, causation and damages naturally follow. But, this is not the ordinary case which we see.

The ordinary case with which we are concerned is where a claimant is seeking recovery for injuries which allegedly were caused by radiation exposure greatly removed in time from the development of the disease or lesion. Of necessity, the greater the length of time passing between the exposure and the development of the "caused lesion," the greater the difficulty becomes. But, this difficulty is not necessarily insurmountable.

We must recognize from the beginning what tort law, confining ourselves to this for an instant, is designed to do. We must not be confused that it, like some social scheme, is designed or intended to spread the loss of a functioning operation to the users of the operation's end product. This is not necessarily a criticism of any attempt to misuse an established form or theory which has, in the past, and is in the present, working effectively.

While certainly change is irresistible, if not desirable, cautious steps should lead to change where the results of change are uncertain. The doctrine of res ipsa loquitur is a rule of evidence which has had its history and present operation, where properly applied, in the field of negligence law. It is utilized as an evidentiary lever by claimants, to explain one of the necessary elements of an ordinary negligence case. It operates where the claimant is incapable, because of various reasons, to effectively prove negligence on the part of his adversary. This theory is available because of the universally recognized logic which attends certain occurrences or circumstances. One intuitively knows that when something happens that it usually had a predecessor known as a cause. Necessarily, that some causes are negligence and cannot be reasonably explained except by human error (negligence), is irrebuttable. This comes about on the basis of human experience and universally-recognized norms of expectation under known circumstances. This universal acceptance and recognized expectation is the very foundation for res ipsa loquitur. For this reason, it should not, however, be available in radiation causes where there is not an immediate development of injuries as the result of radiation exposure, except in rare instances of known high exposure to radiation of an injury-producing capacity.

Naturally, there are some radiation injuries which, in the case of great exposure, are immediately tracable to a known cause. In the event a negligence case were involved in this area, res ipsa loquitur might certainly be used. This type of case, however, is an exception, not the rule. The very basis for this conference is not the exceptional case, but the ordinary case. The ordinary case, as we have said, is one in which small or negligible, or sometimes large amounts, of radiation are received; and usually after the passage of a great deal of time, a lesion, usually cancer-oriented, is claimed to be the result. While it is undisputed, I think, that radiation can certainly be considered to be a factor in "causing" cancer, this causation should be very suspiciously treated until science gives the law a firm foundation on which to proceed with some discretion and intelligence.

Agreed, the cries of an uncompensated injury due to negligent radiation raises a hated spectre. Yet, this cry, except in the most remote instances, is without scientific foundation in fact. The cry of injury without compensation assumes the disputed fact of "causation."

This writer thinks that, if causation were established in these instances, as the hand-wringers assume, most, if not all, of such cases, would result in a recovery, either under a tort theory or workman's compensation scheme, whichever or both might be applicable. Causation, not negligence, is the real thorn in the side of the radiation-insured claimant.

III. - TORT APPLICATION

The methodology of use in handling of radiation sources is so surrounded with statutory, clinical and coded regulations that any deviation resulting in exposure, contrary to prescribed procedures, is almost certain to be negligence. Thus, in the event of claims resulting from an unexpected exposure, investigation almost always finds a broken procedure, a shallow plan or human error. While not all human error is necessarily negligence, it will almost always be so where use of a radiation source results in an unanticipated injury-producing exposure. The danger of radiation use is always recognized, and thus the required safeguards. The possibility of radiation exposure, while not fully appreciated, is certainly not desirable or to be treated lightly. The human animal (the normal juror), whether rightly or wrongly, is now conditioned to the aspect that he wishes to receive no unnatural radiation. It is dangerous, it is generally recognized as such, and is never treated as being of no significance. Therefore, when its use, in whatsoever manner, results in an unexpected or unanticipated exposure, fault certainly is not far away.

Now, assuming for the purposes of argument, that:

(a) An exposure to radiation has occured, and
(b) Negligence on behalf of someone caused the exposure

We then proceed down the chain of essentials necessary to recover in a tort case. Certainly, no one would contend that an act or omission which is negligent and causes exposure, but which causes no harm, should by itself alone form the basis of any kind of monetary liability. There must, of necessity, be damages, regardless of the scheme, before one is entitled to recover for radiation-exposure. Assuming then, as we did before:

(a) Radiation exposure
(b) A negligent act
(c) ______________________________
(d) Damages due to development of cancer

what is the missing element?

The element missing, as any lawyer can see, is proximate cause or causation. Just as exposure by negligent act cannot be the basis of a recovery because no damages have been shown, no recovery can be allowed in a tort case merely because a person develops cancer after he was negligently exposed to radiation. Why is this?

The tort theory is that one should be responsible only for that which he causes. It would unleash a lawyer's field day if recovery were allowed for damages not caused by negligent acts or omissions.

If this were true, an automobile intersection accident could be the basis of a damage action founded upon an unwanted pregnancy. This may be an inept example, since I have been assured by several members of the medical profession that accidents in automobiles have, in fact, been the "cause" of unwanted pregnancy. But, the point to be made is that the causation, not negligence, is the bone of contention in most negligent radiation exposure cases.

IV. - THE FUTURE

Some say that eventual discoveries may prove the harmful effects of a small amount of radiation which now escape compensability due to the failure to prove causation. To them I say that, as the blank spaces surrounding causation are filled, negligence and its ease of establishment, will follow. If later revelations reveal that small amount of radiation are dangerous, then negligence will become more easily proved in those slight exposure cases. Conversely, if further revelations reveal little relation between exposure and the development of damages or injuries, then negligence will be more difficult to prove in any given case, as it should be.

Usually, the alleged long-later occuring damages resulting from radiation exposure is in the nature of some form of cancer. No new type of cancer has yet been identified or associated with exposure to unnatural radiation sources. The cancer which develops is of the same kind and variety which has always plagued mankind, and which was known before the advent of the x-ray, the discovery of radium or the coming of the Atomic Age. It is the same cancer which develops naturally among those who are not exposed to unnatural radiation, and the same seen developing in an epidemological ratio in the general population. The question is then presented, if it is assumed that radiation can cause cancer of varying types, and it is also assumed that the same types of cancer can develop naturally in those persons who suffer unnatural radiation exposure:

WHICH CANCER IS TO BE COMPENSATED?

Naturally, the answer is easily that only that lesion caused by radiation exposure should deserve compensation. Armed with this valid rule of compensation, then we inquire:

> HOW DO YOU TELL THE NATURALLY-OCCURING LESION
> FROM THE UNNATURALLY-RADIATION-INDUCED LESION?

"AYE, THERE'S THE RUB!!!"

The law and its operations should not attempt to be an arbiter of the undeterminable. Perhaps, some day when science has moved so far as to make logical and provable estimates in this area, the law should follow, but no one should be so careless as to suggest that the law should attempt to make a declaration on a common law basis of truth that has no more than a possibility of being accurate.

In an early x-ray burn case (Runyan vs. Goodrum, 147 Ark. 481, 228 S.W. 396 (1921)), the Court, in rejecting its causation, said:

> "The doctrine of res ipsa loquitur does not apply in such cases because the testimony shows that on account of the idiosyncrasies of the x-ray machine, one person of a certain type and temperament would be susceptible to a burn, while another person of a different type, under the same circumstances, would not be burned. Moreover, it is shown that burns do occasionally occur in the ordinary course of exposure, in spite of the highest diligence and skill to prevent them. 4 Labatt's Master and Servant, p. 4864 § 1601 (834), and cases in note: Sweeny vs. Ewing, 35 App. D.C. 57; 43 L.R.A. (N.S.) 734; Wilkins vs. Brock, 81 Vt. 33, 70 Atl. 572."

To further point up the scientific problem and its relation to its legal sister, res ipsa loquitur, the Texas Supreme Court, in discussing causation problems in Jacoby vs. T.E.I.A., 318 S.W. 2d 291, N.R.E. (1958), the Court had before it a case in which cancer had developed at the site of a fractured rib. Justice Bell, in writing the opinion holding against recovery, stated:

> "The law is settled in Texas that, in order for an injury to be compensable under workman's compensation laws of this State, it must be a producing cause. Art. 8306, Sec. 8, V.A.C.S. The producing cause has been defined as a cause which, in a natural or continuous sequence, produces the death (or disability) in issue, and without which the death (or disability) would not have occurred. (citing cases).
>
> "We think this case comes squarely within the rule stated in Joske vs. Irving, 91 Tex. 584, 44 S.W. 1059, and followed in Austin vs. Nieman, Tex. Comm. App. 14 S.W. 2d 794, and in Houston Fire & Casualty Ins. Co. vs. Biber by this Court, 146 S.W.2d 442, 446, error dismissed. judgment correct, in which the rule was set out as follows:
>
>> 'If the probative force of evidence is so weak that it raised only a surmise or suspicion of a fact sought to be established, that evidence and legal contemplation is no evidence and will not support a finding which comprehends the existence of a disputed fact.'"

In the case of Houston Fire & Casualty Co., supra, Justice Norvell had to say of causation:

> "Where the evidence shows that a particular result may possibly have occurred by reason of several different causes, and it is not more reasonably probably that one of the causes was operative rather than the others, a finding of causal relationship between the result and the particular cause cannot be sustained. (Davis vs. Castile, Tex. Comm. App. 257 S.W. 870)
>
> "The medical testimony makes it clear that there are several possible fact situations which may have caused the cerebral hemorrhage suffered by Biber. Among others, There is the possibility that the hemorrhage may have been solely the result of disease. It may have been the result of muscular exertion. It is necessary that some evidence of probative force beyond the raising of a mere surmise be introduced to exclude all of the possibilities before the remaining one can be raised to the dignity of a probability.
>
> "It also appears that deaths from cerebral hemorrhage have occurred when not preceded by muscular exertion or apparent emotional disturbance. These facts leave the element of death solely by reason of disease within the realm of possibility, despite the opinion testimony of the doctor who examined Biber for life insurance during the July preceding his death.
>
> "It is Appellee's theory that Biber, shortly prior to his death, underwent physical exertion or became overheated, and thus the hemorrhage was brought about. This is, of course, a possibility, but can it be said from a proper analysis of the evidence that the existence of this hypothesis is more probably than the existance of the other possibilities discussed?"

Further, the Texas Supreme Court, in the case of I.N.A. vs. Myers, 411 S.W.2d 710 (1967), had before it a case in which a traumatiric injury was alleged to have caused cancer or an aggravation of an existing cancer. On appeal from a favorable judgment in favor of allowing compensation, the Supreme Court reversed same, saying:

> "The causal base of cancer and the theory of its traumatic aggravations are subjects of dispute in the medical profession....
>
> "We have found no case in which lay testimony in the factual circumstances of an injury, together with an expert testimony clearly limited to medical possibilities,

> have been held sufficient to support an inference that a pre-existing tumor was activated and the deadly effects of a malignancy accelerated by an injury.
>
> "It is our view that such occurrence or not is a question of science, determinable only from the testimony of expert medical professionals."

In the only Texas case on the subject of radiation-induced cancer, Employers Insurance Co. of Wisconsin vs. Parker, 418 S.W. 2d 570, Writ of Error Granted, Justice Cadena, of the San Antonio Court, reversed and rendered for the insurance company, in a case where the claimant had received 36 millirems of radiation over a four-year period and developed lymphosarcoma of the neck. He said:

> "Plaintiff relies strongly on testimony to the effect that, assuming exposure to amounts of artificial radiation set forth in hypothetical questions, it was more probable that Plaintiff's cancer was due to artificial rather than to natural or background radiation. However, a reading of his testimony in context reveals the fact that such opinions were based on the assumptions that Plaintiff's tumor had, in fact, been caused by radiation of some kind.
>
> "However, we are convinced, after reviewing the entire testimony, that in this case an inference of causal connection can be no more than speculation and conjecture."

V. - THE SOLUTION

Because of their peculiar propensities and lack of familiarity to the Bar, radiation cases have tended to become segregated into an area recognized by most as being uncompensable. This has, in the main, been the result of the failure of the Bar to approach these new cases with new methods. No new theories are necessary, only diligent and inspired use of those existing is required:

(1) Familiarization with existing and required records of radiation use and exposure are necessary
(2) A scientific approach, based upon facts without gathering emotion is essential.
(3) An understanding of basics and the ability to use a vocabulary concerning radiation and the Atomic Age is a necessity.

Thus, armed with the tools of the "Radiation Trade," a lawyer representing a radiation-injured claimant is formidable. Without these criteria above named, he is a pathetic sight and a disgrace to his profession. Such a lawyer, once embarrassed, is most likely to claim that radiation cases are impossible and thus should be taken over by the "Government" or some statutory presumption passed to aid would-be claimants.

Many studies and much individual work has been done in the are of attempting to define the boundaries of compensation area in radiation injury cases.

One of the more exhaustive studies of the problems in this area is "Studies in Workmen's Compensation and Radiation Injury, Volume II," by Thomas J. O'Toole, sponsored by the U.S. Department of Labor and the Atomic Energy Commission (U.S. Government Printing Office 1965). In Mr. O'Toole's conclusions, he states:

> "The author is unconvinced from an examination of the files in the reported cases that a statutory presumption in favor of the claimant would shift significantly the percentage of cases in which the claim was upheld. In many of these cases, a finding of no causal connection could have been deleted and the same result reached by finding that the claimant had failed to prove an actual exposure to ionizing radiation. In the administration of any statutory presumption, a preliminary decision would have to be made in each instance concerning whether the case actually involved radiation hazards. On this ground, the case could be disposed of and the presumption never come into operation.
>
> "Examination of cases regarding radiation injury reveals conclusively that, where causation is shown, there has been no lack or want of the judicial process to impose liability and the court-conferred compensation."

In the case of Dorr vs. Headstream, 295 S.W. 16, Ark. (1927), treatment with a 4-milliamp machine for eczema of the arm for 30 minutes at a distance of 2 inches produced an x-ray burn, which later healed. Several months after the treatment, an ulcer appeared at the site of the treatment and resisted further attempts at cure. Upon trial, judgment was rendered for the Plaintiff.

In the case of Coover vs. Painless Parker, Dentist, 296 Pac. 1048, a dentist, utilizing x-rays and x-ray machine for treatment, was sued because of the development of cyanosis of the skin, impaired vision, loss of hair, nervousness and generalized swelling of the face in the area of treatment. Upon trial, judgment was rendered for the Plaintiff.

Hiuback vs. Cole, 133 Ohio 137, 12 N.E.2d 283 (1938). In an action sounding in malpractice, a doctor was charged with over-treating with radium a 4-year old child in an attempt to remove a birthmark located on the forehead of the child. After repeated applications and shortly after the last treatment, the skin of the forehead became discolored and the bone structure thereunder receded and remained in a permanently damaged condition. To the defense that the condition was more likely to be sceleroderma, a directed verdict was rendered for the Defendant by the trial court. The Appellate Court reversed, with instructions that from the evidence a question of fact was presented, and that should a jury find causal connection between application of the radium and the injury, then a verdict for the claimant could be supported.

Greenberg vs. Post, 155 Flo. 1 5, 19 So.2d, 714 (1944): The Plaintiff was treated for a nine-year period for removal of superfluous facial hair by the Defendant, the treatment consisting of the utilization of an x-ray machine located in Defendant's beauty parlor. After intermittent intervals, wherein skin discoloration appeared and heavy wrinkles developed, ulcerations began, and finally, toward the last of the treatments, skin cancers developed. Keratosis developed in several areas of the face, and upon an instructed verdict for the Defendant, the case was reversed on the point that the Plaintiff had established a prima facie case of negligence and causation.

Dodds vs. Steller, 77 Cal. App.2d 411, 175 Pac. 2d 607 (1947): Upon an allegation that the Plaintiff had been negligently overexposed to fluoroscope resulting in injuries to his hand, a judgment for the Plaintiff was affirmed and causation and negligence sustained in appeal.

Costa vs Regents of the University of California, 116 Cal. App.2d 445, 254 Pac.2d 85 (1953): Plaintiff received, over a two-month period, some twenty treatments with an x-ray machine for removal of a sore on the tongue. The original sore was cancerous, but the treating physician failed to advise the Plaintiff of this fact. After such treatment, approximately three years, osteomyelitis below the area of treatment developed, resulting in a great deal of damage to the Plaintiff. Upon judgment for the Defendant, the Plaintiff appealed, and the California court reversed, stating that the expert testimony could lay the foundation for the application of the doctrine of res ipsa loquitur on the issue of negligence.

Schwartz vs. Hayden New Port Chemical Corp., 230 Fed. Supp. 536, Est. Dist. Pa. (1964): Schwartz, while a patient in a United States Hospital, received an injection of Umbrathor (later proved to be Curcumin), which was used for dye purposes in a sinus x-ray. Some ten to thirteen years later, cancer was detected, resulting in the removal of an eye and removal of various portions of the face. Schwartz, who was an attorney, was severely damaged, and under the Federal Tort Claims Act, recovered judgment in the amount of $725,000.00, upon a negligence theory.

VI. - CONCLUSION

It is this writer's opinion that Res Ipsa Loquitur is not an answer to those facing a problem of "causation" in radiation cases. Res Ipsa Loquitur is a doctrine of "negligence," not "causation."

Res Ipsa Loquitur will operate effectively in radiation injury cases when science has moved to the point of establishing with a degree of certainty the relationship between radiation exposure and any alleged lesion resulting therefrom. There is no reason to assume that it can operate at all in any radiation case until causation is overcome.

When this day arrives, Res Ipsa Loquitur will operate effectively and justly to settle disputed claims between litigants, for it will then be based on scientific fact established in science, but more importantly, established by man's recognition of expected and predictable results in the face of know circumstances.

RADIATION RECORDS - THE PLAINTIFF'S CASE

W. James Kronzer
Brown, Kronzer, Abraham, Watkins & Steely
Houston, Texas

When Professor Cox phoned to ask that I participate in a seminar or conference "on medical radiation information," I thought he was pulling my proverbial lower appendage. Many of you do not know it but J. L. Cox was one of the best trial lawyers that southwest Louisiana - or the State for that matter - produced before he took the cure and went straight. I have come to know him quite well through my associations with the University of Houston School of Law, and more particularly as a "man in the pits" through our joint handling of a very interesting bit of litigation arising out of the collision of a Greyhound bus with a loaded lumber truck near his hometown in Louisiana.

There is a great deal of levity among lawyers, and particularly those who relate their practices to the courthouse - as I am sure my good friend and worthy "enemy" Tom Alexander will agree - and I thus assumed that this was another "leg-pulling" contest, particularly since I had phoned him about a matter dear to my heart. He kept pursuing the matter as though he were not jesting, and the message finally started getting through. When it became apparent that he was serious, I asked him what he knew about the subject and his expressions of ignorance and innocence paralleled mine. From the easy subject he selected for his own talk, I assume that he has remained equally uninformed.

Following this original conversation in which I agreed to participate upon the principle that anything that is more than 2 weeks off should be agreed to, I had lunch with Professor Cox and Dr. Bushong, and I must say that I became more convinced than ever that I had finally come upon the first seminar or law-oriented symposium in which I would have to confess I knew nothing and could not understand the basic starting points. I recall that I was instructed that I was to have submitted a paper more than 5 days in advance of the commencement of the institute, and that I was to receive an honorarium of some $200. In the past week I have undertaken to do some "research" - to the extent that a noninformed person with no knowledge of the place to start usually does - and all I have succeeded in learning is that I had made a horrendous mistake in preparing to invade this scientific gathering under any circumstances.

I couldn't understand the terminology used in the federal or State regulations, nor could I learn anything of value relating to the levels of ionizing radiation that were considered dangerous or cumulative, and so it is that I waited for the fateful day when Dr. Bushong would phone to ask the status of my "paper." I told him the only decision that I had come to was not to accept the $200 for fear that I would be indicted for theft by pretext. He, being a kindly man, and fully recognizing that he could not bring me to the minimum levels of understanding of the subject, informed me that I could make a few general remarks.

I recall quite distinctly my first observation to Professor Cox after I ascertained that he was serious. I informed him that the only thing that I knew about records from a plaintiff's standpoint is that we always wanted them available, and at the cheapest cost. This, like so many other things lawyers say, is an inexact and misleading statement. Not only is our "science" not truly a science, such as is yours, but its inexactness is often exacerbated by our "open mouth" approach to most problems. The truth of the matter is that the use and admissibility of records is one of the most troublesome and vexatious problems that confronts the Congress, the State legislatures and the courts. The semantical problem is primarily related to the inability of laymen, albeit they may be scientifically trained in other fields, to precisely comprehend the nature of a disputed matter in court.

Each of you has heard of the expression "hearsay evidence," and I feel satisfied that you comprehend what we mean by this term or phrase in a most general way. The reason for the rule against the receipt of "hearsay evidence" in a court of law is what is most easily misunderstood by the public, and particularly the scientific communtiy.

In the law world we are not interested in research and development in its broader or general sense at all; and while our interest may incidentally involve exotic and new frontiers of science, the rules of evidence do not ebb or flow with the size or complexity of the litigation. This is often most perplexing to the scientific mind, as it is of course to the novitiate in our field. I venture to say, however, that any lawyer or judge who has spent a substantial time in the actual practice of law in the courts comes to appreciate the problem of solving and settling disputes in the courthouse and the rules of law pertaining to evidence that limit the receipt of evidence made outside the courts.

Setting aside for the moment these platitudes and beatitudes, you need first understand that all records, wherever and however made and kept, are pure and simple "hearsay evidence." The definition of "hearsay evidence" is that "evidence" which is sought to be introduced without the production of the person who observed the fact or event - or otherwise utilized his senses - so that he might be cross-examined with respect to the testimony he might give. Thus, it is apparent that the preparation, keeping, and/or use of records in a court of law without the production of the declarant or person who actually observes the fact or event recited, or who forms the conclusion reflected therein, is pure hearsay in that he is not in court to be examined with respect to his findings or conclusions.

We of course inherit our system of resolving disputes from our English friends, and one of the remaining graces on that "spit of rock" is the Englishman's continued insistence that the truth cannot be discerned for purposes of resolving private disputes by the use of "hearsay" evidence or information. Of course, the practical considerations that enter upon the complex and changing scene are such that there have been a great number of exceptions to the hearsay rule, and one of these relates to medical records. Yet, most surprisingly, Texas, as well as many other States, did not even engraft this exception on the "hearsay" rule until 17 years ago. The reason for this slowness is the belief by the courts that no exception to the hearsay rule should be developed in the absence of the guarantees of trustworthiness that must be inherent within the records themselves. The courts are simply reluctant to permit any litigant's rights to be determined by persons not ready, willing and able to bring their opinions to court for testing in the crucible of direct- and cross-examination.

I have yet to meet the medical doctor who will accept the premise that any entry he makes into a hospital record, or a hospital or medical record, or official record of the State, should not be accepted as the gospel without requiring him to come down and be publicly embarrassed by a lawyer questioning his integrity, his training, and the amount of compensation he is receiving for his testimony. For years our two professions have struggled valiantly - although perhaps unsuccessfully - to try to make workable rules for courthouse appearances of the expert witness. As noted, we have not met with such success.

You certainly do not have the time today to have a full argumentative explanation of why the slowness of the courts and legislatures to accept medical record testimony is justified to my mind, it being sufficient to note some of the reasons as they relate to the matter before us these two days.

The three problem areas regarding the admissibility of radiation records relate to authenticity, trustworthiness and reliability. "Authenticity" is not merely a matter of proving the record through the proper custodian. It has to do with the accuracy of the recording mechanisms and the criteria utilized by the person interpreting and recording the information sought to be introduced. Herein, it seems to me, lies the principal difficulty with the introduction and receipt of radiation records. I am not personally acquainted with the accuracy of the recording mechanisms utilized to determine the amount of radiation exposure that a person has undergone as a result of a particular incident, or as a result of a group of recurring incidents or exposures. I am not even familiar with the science relating to the cumulative effect of ionizing radiation, but I do understand there is certainly not complete agreement on these questions, nor the variable effects that ionizing radiation has on given subjects. The assimilation of these variables, however, is the threshold problem that the courts will and must assess in determining the admissibility of any records dealing with the effect of radiation.

By way of illustration, each of you is familiar with the fact that the courts uniformly refuse to accept so-called polygraph or "lie detector" tests. The taking or refusing to take such a test is not admissible in any court. This is because of the variables with respect to the subject and the testing personnel. A rather recent interesting but unfortunate experience that I had in this matter of authenticity of records related to my attempt to get into evidence the "speed tape" of a train that struck a passenger car and killed two of the occupants in Sugar Land, Texas. Our contention was that the train was speeding and the engineer made no effort to apply the brakes until he had passed over the crossing. A "speed tape" or "Tackograph" is a recording device which purportedly will show the speed of the train, or large van type trucks, at any given time during their trip. They are required by the Interstate Commerce Commission, and of course are utilized for the purpose of determining that the trains or trucks are not speeding through their runs. In this instance to which I refer, the railroad sought to first introduce the tape to demonstrate that the train was not speeding as it approached the crossing. We thought this would sufficiently vouch for the accuracy and authenticity of the record, and we therefore asked that it be interpreted to show the place where the brakes were applied. An engineer we produced to interpret the tape fixed the point of deceleration shortly after the engine passed over the crossing.

When counsel for the railroad observed the purpose of our use he objected to the introduction of his own tape to show the place where the brakes were applied. The trial court sustained his objection, but the intermediate court reversed and stated that the accuracy of the recording mechanism was established by the attempted prior use of the tape by the railroad. The Texas Supreme Court disagreed with the intermediate court, and said that receiving it for the purpose of showing speed in a general way did not validate the accuracy of the recording mechanism, and that, consequently, the trail court had correctly refused to admit the speed tape. Texas & N. O. Railroad Co. v. Lemke, 365 S.W.2d 148 (Sup.Ct.Tex.1963)

While you can well imagine that I strongly disagree with the holding of our Supreme Court, nevertheless, it does reflect the chariness that the Court has with respect to the receipt of recorded information of a supposedly scientific nature. It has been only in recent years that the courts have accepted without further proof the accuracy of X-ray equipment, speedometers on automobiles, electrocardiographs, electroencephalographic tracings, the results of oscilloscope readings, and similar devices designed to interpret and read the effect of scientific phenomena upon the human body. It is important that it be made clear with respect to this feature of "accuracy" that you understand we are not speaking of the matter of interpretation, but of the inherent accuracy of the recording mechanism itself. Thus, if a person states that he was driving 55 miles per hour, and that he looked at his speedometer shortly before the accident, it is not necessary for him to bring forth expert proof to demonstrate that the speedometer was accurately recording speed. Nor is it necessary for a party seeking to introduce X-rays or electrocardiograph reports to show that the particular machines making the recording were operating accurately as a condition precedent to the receipt of the evidence.

The other facet of "authenticity" or "accuracy" that has plagued the courts relates to the interpretation of the materials recorded by the operator or examiner and the consistency of interpretation regarding the subjects of examination. Notwithstanding extensive business usage of the polygraph - a practice condemned heartily by many - it is highly unlikely that the courts will accept the results of such tests in the reasonably foreseeable future. With respect to this mechanism both the problem of reliability of interpretation and consistency of reaction by the subjects affect admissibility. There is often a subliminal reason to misinterpret, depending, of course, upon who is doing the reading. The now famous "Wally Butts - Bear Bryant" case is an excellent illustration of this weakness. The other enervating factor limiting the receipt of records relates to the variability of responses in different subjects. This is applicable in the polygraph situation, and, as I understand it, is also a problem with respect to radiation exposures and effects. While I am certain that there are levels of dosage in radiation exposure which all would agree are calculated to cause physical responses, including the possibility of death, the problem of keeping accumulation records, or the interpretation of the effect of exposures on a given subject, present very difficult questions for the courts.

Undoubtedly the primary reason for the general rejection of recorded interpretive phenomena in newly developing scientific fields is the problem of "trustworthiness" of the information. This problem is inextricably entwined with the problem of "authenticity," but more directly with the principle that undergirds the "hearsay rule" itself. If there is any possible motive for inaccurate reporting of information, the courts, as you can well imagine, are most reluctant to approbate or receive records. The courtroom presence of the observer or scientist is considered fundamental to this problem. As I have previously mentioned, in our State we had no general statutory rules permitting the receipt of hospital or medical records prior to 1951. See Article 3737e, R.C.S. (act, event of condition). The federal "shop book" rule, 28 U.S.C.A. Sec. 1733 ("act, transaction or occurrence") was extant at that time, but it likewise has some limitations. Generally speaking, the courts have considered information recorded prior to the incident made the basis of the case to have the necessary guaranty of trustworthiness, and it is thus admitted into evidence as an exception to the hearsay rule under these statutory declarations: Kramer, "The Rules of Evidence in Negligence Cases," Practicing Law Institute (1964, pp. 15-17). But the judiciary has been reluctant to receive post-accident hospital or medical records entries that even smack of "diagnosis" or "prognosis." It is not so much that the courts distrust the scientists as it is the desire to give the party affected by the records an opportunity to test both the qualifications of the declarant and to obtain full amplification of the nature of the entry or entries.

Finally, with respect to the use of records in specific legal controversies without the production of the witness, there is the distinct but closely connected problem of "reliability" with respect to "interpretation." It is rather easy to understand this third facet of the problem of admissibility of records when one tests the reliability of the polygraph operator, but it is quite another thing when we speak of interpretations drawn by true scientists, and I am not limiting this observation just to the medical field. Here again, we are confronted with the closely connected question of when the entries and interpretations were made. When we speak of "reliability" in this connection, we address ourselves to interpretative or opinion entries. The most vexing problem to the judiciary relates to the admissibility of "diagnosis" or "prognosis." Most jurisdictions receive medical or hospital record evidence regarding "diagnosis," except in so-called neuropsychiatric injury cases, but reject opinions and records that relate to prognosis.

The Supreme Court of Texas, because of its evident distrust with respect to the use of records of any kind, has engrafted another exception on the Texas statute. In *Loper v.Andrews*, 404 S.W.2d 300 (Tex.Sup.Ct 1966) our highest tribunal held that our statute would not authorize the receipt of medical diagnostic opinions appearing in records "containing *disputable opinion* entries." The court observed that no "opinions" relating to *diagnosis* of injury would be received from records unless "it can be said that the diagnosis records a condition resting in *reasonable medical certainty*." I know of no trial judge or trial lawyer who knows what is meant by "reasonable medical certainty." At least two conclusions can be drawn from this decision insofar as the Texas courts are concerned. First, it reflects the reluctant attitude of the judiciary towards the receipt of record information. Second, it portends that the scientist and medical witness will be required to come to court, dragging his records behind him, when he is undertaking to interpret the effect of observed physical phenomena or conditions.

As I have noted, Texas has probably gone further than most other jurisdictions in *Loper v. Andrews*. Other States refuse to accept hospital or medical record entries that contain "impressions" or "tentative" or "provisional" diagnoses, but none go so far as to say that a diagnostic entry will not be receivable unless it is so certain as that there can be no "disputable opinion." Incidentally, in the *Loper* case the court distinguished an earlier opinion in which a hospital entry indicating that the decedent suffered from "leukemia" was admissible. *Travis Life Ins. Co. v. Rodriguez*, 326 S.W.2d 256 (Austin, 1959) writ refused, 160 Tex. 182, 328 S.W.2d 434 (Sup. 1959). The court concluded that "leukemia" was a diagnostic condition "resting in reasonable medical certainty." It did not, however, indicate that the *cause* of the disease would be treated in the same fashion, and undoubtedly it would not. Specifically, in the *Loper* case a diagnostic conclusion that a young boy was suffering a "papilledema of the left optic disc of about two diopters," and which the doctor "believed" to have been caused by a "fracture of the base of the skull," was not "a condition resting in reasonable medical certainty."

One of the surprising aspects concerning the 1951 Texas legislation relating to the admissibility of federal records is that the language of the particular statute relating to such records is broader than the Federal Act. (Art. 3731a, R.C.S. of Texas) It purports to authorize the receipt of any federal record required to be kept, whereas the federal statute limits admissibility to "acts, transactions or occurrences." Recorded federal market reports have been received under the Texas Act. Missouri Pacific Railroad Co. v. Duncan, 353 S.W. 2d 315 (Austin, 1962, no writ) While such information is not comparable to the interpretive reports, such as would be true of "radiation" records, no doubt the Texas courts would receive federal "radiation" records which are required to be kept to the extent they did no more than report the extent of exposure.

Before undertaking to relate the problem of the admissibility of interpretive information respecting radiation incidents and exposures in the trial of specific causes and controversies, there is one other feature regarding records that should be noted. In medical records, as well as in other areas of human statistic keeping, personal and medical history and the causes thereof are often recorded. This can often be most damaging to a plaintiff in subsequent litigation when the person entering the "history" describes the occurrence in a manner different from that of the party during the trial. When this occurs, the defense customarily seeks to gain admission of the entry and then argue that the true guarantees of trustworthiness were present because at the time of the entry there was no motive upon the part of the allegedly injured plaintiff except to get well. It should be obvious to you that I do not agree with the argumentative approach to entries relating to the history of the occurrence, and fortunately the courts have adopted a wary attitude regarding the receipt of "history" purporting to describe the manner in which the accident itself was caused. Except with respect to police and investigative records, there is no general guarantee of trustworthiness with respect to such a "history" because the person making the entries is not concerned with the fault arising from the accident, but only concerned whether the history outlines the nature of the injury and the type of medical treatment necessary. Appreciating this, the courts have only admitted such evidence of history under tied down circumstances. See annotation, "Admissibility of Hospital Records Relating to Cause or Circumstances of Accident or Incident in which Patient Sustained Injury," 44 A.L.R. 2d 553 (1955). The courts also reject prejudicial irrelevancies, such as the disastrously prejudicial remarks of caseworkers that are themselves founded in double hearsay. Roberts v. Dallas Railway & Terminal Co., 276 S.W.2d 575 (El Paso Civ. App. 1953, writ ref., n.r.e.)

Trying to relate these general rules regarding the admissibility of records to the problem of keeping and gaining admission of "radiation records" in the trial of disputed cases is a most difficult task for the uninitiated, such as myself. It is necessary to distinguish the keeping of records in the public interest, or for research and development, on the one hand, from the use of record information in the trial of particular controversies. We must even distinguish this from the receipt of such matters in administrative hearings relating to persons and entities handling materials capable of "ionizing radiation." Both the Congress and most of the States, including Texas, have promulgated specific legislation with respect to the keeping of records regarding radiation, and the power of the various regulatory agencies to enact reasonable rules and regulations for the obtaining of this information. Under both the federal and State acts the agencies are entitled to and do conduct the inquiries into the reasonableness of requiring records to be kept regarding the use and exposure of such materials. You are no doubt familiar with the continuing hearings of the Product Safety Commission, organized under 5 United States Code 552, and known as the "Freedom of Information Act," with particular reference to automobile defects.

The important thing to realize, however, about this type of record keeping in the public interest, or for research and development, or for the correlating of scientific information, is that a great deal of such valuable materials would never be admissible in a court of law. For example, a determination by the U. S. Department of Transportation under the "Motor Vehicle Safety Defect Recall Campaign" that a particular model of an automobile is known to have a potentiality for accidents because of a possibility of a defect in some mechanism would not be receivable in evidence to establish the existence of a particular "defect" in the subject case. This again may appear to be metaphysical insofar as you are concerned, but it demonstrates another facet of the principles of legal relevancy and materiality. The courts simply do not permit a party to establish a defective condition upon the law of probabilities from records. It is necessary that the parties seeking to prove that fact establish it by independent testimony from witnesses during the process of court examination.

This is not to say that recorded information of the type contemplated by the federal and State authorities with respect to radiation would not prove helpful to the injured person. To the contrary, it can be vitally helpful in developing his case for trial. The experience gained from the correlation of such information over a substantial period of time is bound to formulate the opinion of the individual observers who are experts in these fields. Perhaps even more importantly, such recorded information can be effectively utilized against live witnesses who purport to testify as to the improbability of a defect or the causative relationship between a particular bodily condition and the scientific phenomena alleged to have produced that effect. In other words, if the expert witness takes the position that the radial ply tires on a Mercury Colony Park station wagon factory equipped with such tires cannot fail, it would then be permissible to show that some 356 cars had been recalled because of the "possible sidewall crackings at relatively low mileage which could eventually result in tire failure." See "Motor Vehicle Safety Defect Recall Campaign" from September 9, 1966, to December 31, 1966, reported to "The National Highway Safety Bureau." In this context it is readily apparent that such information can serve a vital and valuable purpose to a plaintiff.

The much more difficult problem relating to the "keeping" of records of radiation exposure by medical persons or other persons with expertise in this area is not clear to me. Of course, we lawyers are not capable of appraising the value of record keeping of cumulative radiation exposures from a medical and research standpoint. It occurs to the uninformed that to the extent that latent or dormant conditions predisposing to leukemia and similar blood diseases are aggravated or accelerated by repeated or accumulated exposures there would be great value in requiring the keeping of accurate records, at least where there have been intentional exposures such as by the use of X-rays. The offsetting factor would be the cumbersomeness of such records, the burden upon the expert to record such information, and the potentially small correlative value that could arise from the collection of such information.

The more important question from the legal standpoint is what value could be made of such records in the event of a legal controversy. There are two aspects of this potential use of such records. First, there is the possibility of using such records in a malpractice action against the doctor or doctors alleged to have caused or brought on the fatal or injurious disease or bodily condition. No doubt from a records standpoint, in such situations the previous exposures would be valuable from the plaintiff's viewpoint and would be admissible in evidence. Thus, in this selfish respect, it would be my belief that considerable help could come from the keeping and availability of records reflecting prior exposures to ionizing radiation. While the word "malpractice" causes the "hackles" of the doctors to rise - and I assure you it does the lawyers also - a plaintiff, or his beneficiaries, is a long way from home by merely having the records available even in usable form.

There is no reason to assume that the courts will deviate in true radiation injury cases from the general principles that have been applied to such exposures in X-ray treatment or diagnostic cases. The rule in such cases is like it is in all medical malpractice cases, and that is that mere statistic keeping is not a substitute for the necessary live medical witness who will testify that the manner of treatment constituted a lack of medical skill in the community where the alleged injury occurred. See annotation "Injury by X-ray," 41 A.L.R.2d 329, 333 (1955); Karlovec, "X-ray Malpractice," 11 Cleveland & Marshall Law Review, pp. 266-271 (1962); Hamilton v. Harris, 223 S.W. 533 (San Antonio Civ. App., 1920, writ dism.) As the textwriter in the American Law Reports, Annotated, states:

> "It is commonly, but not unanimously, held that in malpractice action, recovery against the physician or surgeon requires expert testimony; on this point, holdings both ways are to be found in X-ray injury cases. With regard to the expert testimony issue, it may be noted that the courts generally have been

> liberal in ruling on who may be regarded as an expert in X-ray injury cases; X-ray specialists not practicing in the same community as that in which a defendant practices, physicians not specializing in X-ray work, nonphysician X-ray workers, and chiropractor (but not a chiropodist) have all been qualified to testify as experts in actions of this kind."

A reading of the cases, however, does not indicate that the courts have substantially deviated from the general rule requiring the production of medical testimony of persons similarly qualified in the community where the X-ray or radiation exposure occurred. Certainly Texas has not deviated. In the Law Review article noted, the conclusion is drawn:

> "Many of the old cases of malpractice arising out of the use of X-rays appear to have been a result both of ignorance of the patient and general carelessness of the treating physician. To date, however, with the word radiation much in everyone's mind, the public is alerted, and the physician need only inform the patient of the reasonable expectations from this therapy."

The second feature of required cumulative record keeping that would undoubtedly prove helpful to plaintiffs relates to compensability arising under Workmen's Compensation Acts as an "occupational disease," or the superimposition of traumatic injury which might accelerate or precipitate the onset of the disease of a person predisposed to it by reason of prior exposures. For example, the Texas Workmen's Compensation Act provides for compensation benefits in the event of injury or death from radiation exposure. Surprisingly, one of the provisions of the Act relating to prior exposures would probably not have the effect of reducing the compensation benefits arising from the last exposure, at least if the prior exposures occurred during the employment of the injured or diseased employee. Article 8306, Sec. 22, R.C.S. In any event, the keeping of records would be most helpful in the handling and disposition of compensation and personal injury cases, whether treated as an "occupational disease" controversy, or as an "accidental injury" arising because of a claim of acceleration of a dormant or quiescent cancerous condition. See Insurance Company of North America v. Myers, 411 S.W.2d 710 (Tex. Sup. 1966) It probably does come as a shock to some of you to know that the courts have long had the answer to the causes of cancer, since the courts have recognized the validity of expert medical evidence that trauma can at least excite or accelerate a dormant or quiescent predisposing condition.

There is one additional interesting aspect of radiation injuries, and the effect that records might have in legal controversies, and that relates to the concern of the Congress and the State legislatures over radiation exposure. For example, in Texas and several of the other jurisdictions which are parties to the "Southern Interstate Nuclear Compact," the Legislatures provided in 1963 that the governing boards of the State institutions of higher learning performing experiments in the field of nuclear science, or any other governmental agency engaged in such research or development, are authorized to purchase liability insurance in an amount not to exceed $250,000, and, most surprisingly, the defense of sovereign immunity is expressly waived in such situations. Art. 4590g, R.C.S. This of course does not affect the medical doctor directly, but it does, however, expose the State institutions and State-supported colleges through the insured liability up to the maximum amount provided in the Act.

In sum, when you understand the limitations that the courts impose upon the receipt of records of any kind, and the reasons for these proscriptions, you can comprehend the rather limited value that would come from extensive record keeping insofar as the courthouse is concerned. For my part, I would have it no other way, particularly so long as the scientific data cannot be correlated and observed with such exactitude that there is no margin of error. We lawyers are slow to give up the right to confront the expert witness. There is no doubt, however, that the courts would receive those portions of "radiation records" which detected the amount of prior exposure or quantum and quality of exposure incidents. On balance, this type of information should prove helpful to complainants. Interpretive opinions in such records undoubtedly stand on a different basis, and I would hope the Congress, the State Legislatures and the courts would not legislate or require the receipt of such "evidence" without the supporting live testimony of the declarant.

Frankly, I am incapable of expressing a value judgment as to the contributions to the judicial community that might be made by required record keeping at the expert level with respect to all radiation exposure. No doubt there would be substantial reaction and reluctance to collect and report such information, if for no other reason, because of the belief that the burdens far outweigh any potential value. I can unequivocally say, however, that from the plaintiff's viewpoint the collection and availability of such information carried without opinion and comment, would be of great value to persons sustaining radiation injuries, or who suffer from diseases that are arguably traceable to radiation exposure.

RADIATION RECORDS - THE DEFENDANT'S CASE

Thomas Alexander
Butler, Binion, Rice, Cook & Knapp
Houston, Texas

May it please the Court; ladies and gentlemen.

This is a unique opportunity in that for the first time that I know of, I get to follow Mr. Kronzer, rather than let Mr. Kronzer follow me. I was very interested in his style, and his approach, not as an advocate, but with an advocate's approach. I study Mr. Kronzer a lot like George Selkerk studied Joe DiMaggio when Joe DiMaggio was playing center field--not that George Selkerk could ever do what Joe DiMaggio did, but he just wanted to remind himself from time to time of how much room there was for improvement.

I feel the same way. Mr. Kronzer has used one of the most effective speakers' devices that I know. I wasn't looking at the audience at the time, but I suspect that just about halfway through the speech, a few people got to nodding a little bit, so Mr. Kronzer did what was necessary to get doctors back on the track. He mentioned malpractice. I could hear the chairs rustle and the wallets shuffle when he did that. Also, just for good measure, he jumped one of the men from the insurance industry.

If the insurance industry ever quits, Mr. Kronzer would have to find himself a new forum for his advocacy. Let me say this, too, while I'm on the subject of the insurance industry. We are here on the program as representatives, so to speak, of a plaintiff's point of view and defendant's point of view. It would require a great deal of time and a man more articulate than I to explain the role of an advocate in our adversary system and the role of that adversary system and a lawyer's in our society. I won't go into that now.

But, neither of us is here as an advocate of a personal point of view toward the development of the law. In fact, if anything, it's just the opposite. I think if there were a test, as I've heard Jim refer to, in which you measured radiation doses; if you measured doses of conservatism and liberalism as far as the development of the law is concerned, I would probably measure more liberal than the Big Man -- and Mr. Reporter, when I say the Big Man, that's Kronzer, spelled K-r-o-n-z-e-r.

But, as far as the insurance industry is concerned, I know of no one in the insurance industry who's approaching tort problems from the point of view that tort actions should be eliminated. I don't think so at all -- at least, I don't think that is so about the insurance industry. What I do know about the insurance industry is that they want a system through which they can pay the claims they owe; but also, through which they do not have to pay the claims that they don't owe. Now, that may sound like a fairy tale or pie in the sky, but I don't hear any men from the insurance industry that are anxious to do away with the system we have. There is no system that I know that works better than the adversary system that we have, whereby disputed facts are submitted to a jury with each side represented by a capable, well-armed and well-paid -- and that is important -- adversary to develop each side of the case so that the fact-finders -- the jury or the judge, whichever it may be -- can then find truth.

Now, we have explored a lot of subjects and that really leads us to a discussion of records here today. Jim has talked about hearsay evidence and our abhorrence of hearsay evidence. We are very reluctant to accept it, because we know one effective tool for finding facts -- we know that our adversary system works. We distrust anything that would replace it, knowing full well and recognizing that our adversary system is cumbersome; it's slow; it subjects people to a lot of inconvenience, particularly, the doctors. We have to get you fellows down -- under subpoena or not -- to relate your version of the facts that you are close to and related to, and to cross examine you so that the jury can then determine -- or the judge -- what the true facts are.

Now, many of you understand that and many of you don't. And as I say, that's the topic for another speech on another occasion, and I hope that you will give me an opportunity to make that speech on some occasion someday, because doctors really need to understand that. But, for this reason, because we know that we have an effective, workable system and we know that this system does as much as anything we know in our practice to eliminate over compensation or exaggeration -- by the same token, to prevent the reluctance of an insurance company to pay a claim that they have some question on or some doubt; this same system forces things in that event, if the claim is good and justified.

Now, when we talk about substituting records for the appearance before that jury or that Court of the proponent of a particular point of view, that is, has this person suffered from excessive radiation and if so, why and what are the effects and what, in reasonable medical probability, will be the future effects? Now, if we surrender our duty under the law to get the proponent of that idea before the fact-finder so that the fact-finder can observe the proponent of that idea as he gives his evidence and so that the adversary resisting that idea can test that idea with facts, with records -- the records that are entered are very useful to both sides, when we have the proponent of the idea there to be tested on his ideas.

But, we have a tendency -- both as lawyers and as human beings-- to sometimes accept records alone as facts, or records as ultimate truth. I can cite a number of examples: As Mr. Kronzer says, all plaintiffs love records. Now, I really like that statement.

I hope you got that, Mr. McCracken, because I have seen the situation in which my friend, the Big Man, didn't like those records so much. And by the same token, situations in which I didn't.

I recall one occasion in particular where he was representing some poor citizen that was the victim of society and in particular, the victim of a rear-end collision by an oil company truck. And as a result of this collision, this fellow couldn't move anything but his eyes, and just barely could do that. For ten minutes after he moved them, he had to rest. He walked around keeping his neck straight and stiff and the fellow's case just dragged on for a long time, because I was otherwise occupied and when I wasn't, somebody else was or the Court was tied up. And this is one of the present problems -- I don't mean to make light of the problem, but at any rate, this fellow thought that as long as the lawsuit was pending and he wasn't doing anything anyway, he might as well move off up to Dallas and find himself a nice, executive-type job. So, he went to Dallas and found one of these employment agencies that advertise that they have executive jobs available. But, anyway, they have a lot of magnificent, marvelous jobs available. And to make it all the more plausible, when one of these prospective clients comes in, they give him an awful lot of forms to fill out.

One of the forms that this gentleman filled out was labeled Assistance to Personality Evaluation -- whatever that might be -- and had a number of questions asking this fellow to describe himself. And he described himself in the most glowing terms, naturally, thinking that it would be a good prerequisite for employment. But, one particular question that I remember -- there were many that damaged his lawsuit; filled out in his own hand. But, one of the most damaging in the record that he filled out was: "How do you go up and down stairs?" Well, this fellow didn't want to say, "I'm so bad off that I get my wife to come and help me up and down because I'm disabled." In fact, he didn't even say, "I get up and down the best way I can." He says, "Ordinarily, I take stairs two to three at a time, because I'm very anxious to get where I'm going." This record was one, at least, that the Big Man didn't like.

Now, the law in Texas about records (article 3737e, The Business Records Act), simply put, is that we will admit records that are kept in the normal course of business in some business endeavor if the entries made in these records are made at or about the time of the transaction reflected in the entry and by a person who had direct knowledge of the transaction. But, we modify that to this extent -- as Jim says, we don't want any opinions in those records. For a good reason on both sides.

As an example, for instance, hospital records are admissible under this act -- and it saves a world of time and a world of trouble and really gets at the truth, to admit hospital records, if we confine those records to proof of the facts as to situations about which there can be no medical difference. For instance, if the hospital record shows that Joe Doaks had a broken leg and was treated for a broken leg in that hospital on August 3rd, 1966, that is admissible. A broken leg is a diagnosis about which no one can disagree -- except very picky people -- and there are some questionable cases. But on the other hand, if the hospital record says that, in the opinion of some scientist with an M.D. -- the patient is a malingerer, well, we can't allow that into evidence without getting that scientist down and saying, "Wait a minute. Upon what did you base your conclusion that this man was a malingerer?" Because medical minds can differ on that opinion.

Now, these records are particularly helpful to the defendant when the plaintiff's doctor comes to court and says, "Why, this man is truly disabled; he'll probably never hit another lick," and the hospital record that that doctor made himself when he was on the surgical staff at Methodist Hospital says, "This man is a malingerer," then that goes kind of hard on that doctor. But, as original evidence, that record is not admissible.

While we're on hospital records, I remember one situation which did not involve the Big Man, but one of his compatriots, where they had one of these fellows that had that national catastrophe occur to him, that is, he had received a neck sprain. And he immediately placed himself in the hospital, in that he had been hit by a solvent defendant from the rear. He put himself in the hospital to have his neck stretched for a while. I don't know what good it does, but it doesn't seem to do anybody any harm. And this fellow languished around in the hospital for a while and ran up a seven or $800 hospital bill and the treating physician, likewise. So, they made a claim and based it upon those high medical damages, demanding a substantial amount of money.

And, as I ordinarily do, I subpoenaed the hospital records. Nurses are the most accurate, factual people in the world; they are a breed unto themselves. They have no hesitancy to tell it like it is. I find a lot of interesting things in nurses' notes, some of which I couldn't even relate here. On this occasion, on the second night of this poor citizen's stay in the hospital, while he was undergoing all this therapy, there appeared a very terse note in the nurses' records that at 3:00 a.m. the patient "attacked LPN in hall and had to be restrained, was put in bed with sedative." That decreased the value of his case a little.

Fortunately, he had a lawyer that I could talk sense to. I showed the lawyer the note and he discussed it with his client, and they decided that they'd wait until the next whiplash injury.

But, anyway, as far as records themselves are concerned, if we are using them as a vehicle towards truth, they're valuable. Every trial lawyer that I know -- every trial lawyer that is competent, at any rate -- recognizes that, appreciates that, and wants to utilize it.

It's really not our desire that litigation be as prolonged as it is. It's not our desire that litigation be as expensive as it is. Any time we find any helpful aid to reduce the time of litigation and reduce the fees we have to charge, we utilize it. But, at any rate, where records are helpful towards reaching truth, we welcome them, appreciate them. I think that almost all others who have been in contact with our adversary system and have seen its application by competent lawyers and the results reached by serious-minded jurors will join me in saying that this is the best vehicle known to find truth. And I say that not because I'm trying to resist any effort to establish ultimate results by some other means, though I would resist on that ground alone.

But, about records themselves, I notice on the program, one of the topics and one of the inquiries was the question of privilege. Under Texas law, there's nothing that a doctor says, does or records, or nothing that a patient says, does or records to his doctor that is in any way privileged whatsoever. We have no such thing in Texas as a doctor-patient privilege. Now, there are reasons for and reasons against that, and the validity of it is again the subject of another talk. And I imagine the Big Man and I could debate that pretty long, if we really got after it. But, bear in mind, please, that any record you keep is subject to discovery in any proceeding of any kind, whether you are involved in it or someone else is involved in it, in which that record is in any way relevant. And that is pretty broad.

Now, that also should be considered in regard to keeping records. You know, we must remember the tendency of everyone, laymen and lawyers alike, and especially doctors -- I find this; I don't say this critically, though it may be taken critically. But, doctors always want the answers as soon as possible. They are not trained like lawyers, to seek the answer over a period of time, or an involved procedure. Doctors want to be able -- and I suppose we really all want to be able -- to put down a set of figures over there and a set of figures on this side and add the figures and say, "This is the total over here and this set reaches a higher total than this set, therefore, this is the better plan."

Well, we assume a lot of things when we reach conclusions on that basis. We assume, first, the validity of the record. We assume the application of the record to the individual subject of the inquiry, which is a very big step; and evidently, a step, according to what Jim said in his talk, that the doctors are not prepared to make in regard to radiation exposures. You know, in that connection, I'm reminded of a situation in which records were subject to several interpretations. I had a fellow one time that was suing my client for a large sum of money. And, of course, in that regard, his employment record became material. I subpoenaed his employment records from the several employers he had had, both before and after the accident that was made the basis of his suit against my client. Now, in going through those records, it became apparent to me that this fellow had missed a lot of work, both before and after the accident. Also, it became apparent when we checked the records that he had missed an awful lot of Mondays. Now, one would be subject to jumping to the conclusion that this man had some trouble with alcohol. That's a popular notion. In fact, it's run in the newspaper or magazine advertisements -- not of late, but I've seen it before.

Most everyone would assume that with such a record, this fellow does have trouble with alcohol. And he may. I don't know. But, the point is the record alone doesn't establish it. Now, that record would be admissible in court as to the days he missed and as to which days of the week he missed. But, if the personnel director had put in there this conclusion -- which he didn't, but just imagine if the man put in there this conclusion: "This record tends to establish alcoholism in this employee." Then that portion of the record would not be admissible. If I wanted the personnel director there to state that conclusion, it would be up to me to bring him there. And if he had other basis to state an opinion, then, he would be allowed, of course, to state that opinion based upon his observations, but not upon the record alone. Also, he would be subject to cross examination by the attorney for the claimant.

Now, while that record may not look good, it may be just the opposite. In fact, it may well be that this same citizen had no problem with alcohol at all, but on each Sunday became so overcome with religious fervor from attending various church services that on Monday he was unable to function. While that likelihood would be, what was that word - probabilistic - the probability may be that the fellow was an alcoholic, but we can't let his situation be determined by a probability. We can't let that man's rights be determined by such a degree of probability, though that may be what the majority agree on -- in other words, there may be a 60 per cent probability as opposed to a 40 per cent probability. We can't allow that. We know a better way to find out the truth about the situation. And as long as we know a better way, it would be a sin and a shame, and especially to that particular litigant, not to use the better way, even though it may be more expensive.

Mr. Tressler, I know that that is a problem that you face, but as long as we have an effective tool available, we cannot surrender that tool to litigation by records alone until we are absolutely certain that truth will be found in that way, just as it is in the way we know the truth can be found.

One problem that the defense has in these cases -- and I speak of cases in general, as well as radiation cases -- is the proposition that under our system, anybody with a medical degree and a medical license can come to court on behalf of any plaintiff or defendant; and if he's modest enough to admit that he is qualified as an expert in that particular field, whether you as doctors would agree that he's a qualified expert or not; and if he admits that he has an opinion based upon those qualifications, however meager, and upon his observations and treatment or based upon a hypothetical situation; and if he is willing to express that opinion, he may state to a jury, for instance, in a case in which you would think -- and probably be right -- that that particular doctor had no business expressing an opinion on whether or not the plaintiff, for instance, had skin cancer as a result of overexposure to radiation at the hands of Dr. X who had been treating him for some other purpose, then he may state that opinion.

Now, it does not sound good initially that that opinion is admissible into evidence regardless of whether or not the stater of that opinion has particular qualifications in that particular field. But, the reason that is admissible is because we have no way other than our adversary system of determining who is qualified and who is not qualified to state that opinion.

It would not be right, for example, for me or Mr. Kronzer or the combination of the two of us, if we could ever agree on anything, to go through the medical roster of Harris County, say, and say, "Dr. X is qualified to testify on radiological matters only," or, "Dr. Y may be able to testify in internal medicine problems," and just go on down the list; "Dr. Z is not qualified to testify at all."

Our system thrives upon the fact that in each individual case, the person who makes the decision -- or the persons who make the decisions -- as to which opinion is to be followed or accepted are the people that have heard those witnesses testify, have heard their qualifications tested by the lawyers involved; heard their interest in the case tested by lawyers involved; have heard their opinions tested, if you please, based upon medical literature or based upon things that this particular physician may have written himself, in records or the literature. And through this testing; through this grist mill, for lack of a better term, truth results. Now, this grist mill is a little hard, especially on the doctor who may be involved. I've heard a number of complaints voiced about it. But, it's necessary that your qualifications be tested; it's necessary that your interest in the case, if any, be tested; it's necessary that your opinion be tested. And I submit to you that many of you would be much better off if you tested your own opinions by the same standard -- that is, what would I say in court if I were asked? What is my basis for this? What are my qualifications to express this opinion -- before you put the opinions in a hospital record. And the same with a radiological record.

Doctors love certainty, which is not unusual. Everybody loves as much certainty in their life as possible. It's awfully hard, for instance, for a doctor to understand why some people with neck sprains do not get well in four weeks. Doctors know people with neck sprains with no nerve root involvement and no other evidence of any internal injury should be well in four weeks. They know that. But, some of these rascals won't get well in four weeks. And they are certainly not all faking. In fact, I really believe, from the ones that I see, that a very small percentage of them are out and out fakes. They have a lot of other problems. His wife, for years, may have been ignoring him, but, now all of a sudden, he has his neck in a harness and his wife is fixing his supper early; fixing what he likes, and he likes it pretty well. He's liable to go for half a year with that neck brace.

There are a lot of reasons that these things go on, not all defined. So, maybe its subconscious, maybe it's faking or a mixture, but those matters are hard to determine. By the same token, it's awful hard for doctors sometimes to understand how a fellow with a neck problem and a positive myelogram ever gets well. They look at the positive myelogram and say, "Well, there's no way for that fellow to recover except by surgery."

Some of these guys really know better than the doctor how bad they are hurt. And they say, "Well, I think I'll wait a while for that surgery, Doc." And then, pretty soon, as time goes on and their case gets settled -- and I don't mean that in any way but facetiously. When they get the worry and bother of litigation behind them -- let's put it that way -- all of a sudden, they don't have the problem any more. It's hard for the doctor to understand. Now, this is the same doctor that came to court and said, "This man has a positive myelogram. He'll never be well short of surgery." All of a sudden, this fellow is back playing baseball again and skin diving and water skiing. That's hard for the doctor to understand, because, when you deal with people, as Jim and I do all the time; they are the only constants in our business. Every case is different because it involves different people. Every jury is different, because there are 12 different people. Every Court is different, though they try to be uniform, they cannot be.

It's the same, really, as in your practice. And the idea of reducing matters to records for the purpose of determining truth is defeated, I believe, in a large measure in that regard. Now, the use of records as an aid to determine truth is valid. But, the idea of using records alone for the purpose of developing ultimate truth, I think, is based upon a false premise and will never be successful.

There are a few other points I'd like to cover; that is, the tendency to overvalue, or over-emphasize records. I agree that it's ordinarily a good idea to keep records. That's hard to fault. I mean, you ought to have a record of what you do. The government takes that position in regard to income tax. As a matter of fact, they're a little narrow about it, really. But, it's not a bad idea to keep records. But, you must evaluate your records. You must know what kind of records you're keeping and what you are expected to show, and what you expect them to show you.

Now, if your records are kept for the purpose -- the sole purpose of either establishing or ruling out a medical diagnosis or a medical situation or an overexposure or underexposure to X-rays, then I question the validity of them. If they are used as an aid toward trying to determine when some trouble develops, whether or not this trouble is related to a particular exposure or a series of exposures, or unknown sources or oversensitivity, then, I submit records are valuable. But, valuable only as a tool for the man interpreting the records and trying to reach an opinion of the situation based on proper qualification.

As a corollary to that, I'd like to mention a cancer phobia case in New York. I won't try to relate it exactly, because I don't have it fresh in my mind. But, the patient had been treated by one doctor for some purpose or another and developed some skin lesions, whereupon, she went to another doctor. Upon arriving there, he made a mistake that I have heard in lots of situations, that doctors ought to think about before they ever use this expression. The new doctor immediately said, "Who did this to you?" Now, I've heard that in my practice, and I'll bet you have, Jim, at least a dozen times. Actually, I don't think they mean to imply to the patient that some ham-handed physician -- or practitioner -- has ruined your life. But, it certainly sounds that way, because the patient has gone to the new doctor because of concern. At any rate, this patient came to the new doctor and this doctor said, "Who did this to you? This could cause cancer, and I believe it probably has." Well, it turned out that it hadn't caused cancer at all. But the statement caused or precipitated a complete, irreversible neurotic state in the patient to the point that she now had what they call cancer phobia. You might be familiar with that. I wasn't until I read this case. But, she was convinced, and nobody was ever able to effectively convince her otherwise, that she in fact had cancer. She sued not the doctor that allegedly had caused these lesions, but the doctor who, because of his quote that "this is probably cancer," had caused a cancer phobia and she recovered from him.

For purpose of encouraging you in this study of the use and efficacy of records in determining exactly what you want to use them for. What use do you want to make of them? I can see, for instance, a cancer phobia situation resulting from careful, chronological recording of a person's own daily overexposure to X-ray when, in fact, it had no physical effect at all.

The other matters that I want to refer to in regard to records themselves are the importance of, if you keep records, having some systematic way to keep and file your records. We run across this, not just with doctors, but in every situation. People tend to keep just about half of everything. For some reason or another, the other half is lost. But, all of a sudden, you get in litigation and somebody subpoenas your records and, "This is the first time I knew about it. What am I going to do? I don't have all the records." Well, as soon as they get there, an intelligent lawyer is going to say, "Look. You've omitted part of these records."

And you say, "Well, I lost them."

"You mean, you've lost the key records?" The inference is that you haven't lost these records at all; that maybe these records were the ones that showed an overexposure to radiation.

You see, these are the problems you get into, and the problems that are brought about by just willy-nilly, half-heartedly, with half purpose keeping records. That's why I believe, as an advocate, that records should be used not for the purpose of establishing ultimate facts, but for the purpose of aiding you when it comes time to establish the ultimate fact, and that records must be kept with some idea in mind as to the purpose, the eventual validity that is hoped for, and with care.

Thank you.

DISCUSSION

DEAN NEIBEL: Let's have a change in the program at this point and entertain questions and discussion.

DR. GOLDEN: What about the institution that maintains exposure records?

MR. KRONZER: Particularly when you're dealing with licensed sources, you have to keep records in Texas and elsewhere. Those are the kind of records we really enjoy from the plaintiff's standpoint, to see that you're keeping them. The non-keeping is what we like to have most there. But, the private keeping of records by people that are using isotopes either under special license or a general license and the records of radium activity, radium use, or isotope use in the practice of nuclear medicine, are generally required and certainly those are the kind that are helpful.

Now, your industrial records, from what you all say I don't see how they mean anything. You've got exposure to the hand, a rem and rad count, and a place that tells you how much he had in his lifetime--I don't know any court that would accept those records.

DR. GOLDEN: I'm sorry. I actually phrased the question wrong. I'm thinking in terms of those who generate their own records, like running their own film badge service. Are these as valid as records developed by an outside company?

MR. KRONZER: As Tom says, under both the Federal and State--and this applies pretty well throughout the country--those records that are kept in the regular course of business, they're not required by statute or law, but just voluntary records and you keep them regularly; you consider them as a part of your business; the entries on them are made about the time the act, event or transaction that they reflect occurred and by the person who observed that fact or measured that fact; those records are admissible for or against you, or against your institution, regardless of statutory or legislative sanction or disapproval of the keeping of records.

Do I make my self clear? In other words, they help you if they support your position.

DR. GOLDEN: Well, does the institution that generates its own records stand on a firmer base than one going to an outside company to measure radiation exposure, say, by film badges?

MR. KRONZER: Well, it's very difficult for me to shift my gears to the defense side. But, I would say generally, it's better if they don't go to an outside source if they're under question and litigation. They'd have been better with their own records than they might have been outside, unless the outside sources corroborated what they've been doing all along. We, from the plaintiff's standpoint just love to get records outside the particular entity or agency that support our position. You understand what I'm saying? This is very helpful from our standpoint.

MR. ALEXANDER: May I comment on that?

Aside from the subject of my talk, which is just the question of records from a lawyer's point of view, I would suggest to you that the very first consideration regarding whether or not to keep records and what to do with them or what kind of records to keep, should be a medical question.

That is, records should be kept with a concern for medical questions that might arise, as to whether or not you are in fact subjecting employees to overexposure.

I think the question of the records' eventual use in lawsuits should be purely incidental. If you keep records on a private basis, you will be able to examine the results from day to day; and you'll be able to direct the course of your inquiry.

Of course, you could do the same with an outside source, but I would say that it would be a good idea to keep your records based upon what you think is important, or what you think may be relative. That is, aside from the standards that have already been set up for record-keeping.

DR. GORSON: I'd like to raise a point that both of you pointed out; namely the distinction between the record in itself and an interpretation of the record. Now, as I gather, when it comes to the interpretation, that's an opinion of what the record means. That is something that is useless to you unless the expert is available to the court for cross examination and determination of how he arrived at the conclusion. Now, what about the situation when you have records that have been accumulating over many, many years and during the process of accumulating the records, the individuals concerned--the experts concerned--render opinions continuously on the records and those persons are no longer available at some future date when the records become important and are questioned? Is that opinion which is rendered on the records completely useless at that date?

MR. KRONZER: His absence isn't important to that decision. His death or absence is not important unless he was a party or a person who made a statement in the records that was against his interest at the time he made it. In other words, records are a single, separated entity that are taken out of the hearsay rule, because of its authenticity--that is, the accuracy of the mechanism of recording; that's one thing. The second thing is the reliability of the reporter. Now, when you get to that point, if there is a difference of opinion as to what an interpretation means, for example, if you say that this dose was getting close to a dangerous dose, and that appears in the record, so far as I know, there isn't a court in the land that would take that opinion, whether the reporter was gone to Timbuktu, or is here, live and kicking. Because, they say, "You come down there and tell us why it's so." As I understand what you folks say, there's just not that much everyday, garden variety truth in what you record concerning exposure; where you don't even know the rate of accumulation as I understand what you say. That being true, your drawn opinion is not indisputable. It's not that you can't come express it. Yes you can. But, when you do, you drag your own records behind you.

DR. GORSON: This is what actually happens in practice. In the case of recording radiation exposure by personal monitoring devices, you get a whole spectrum of reports. And then, if the readings are high enough, you take a look at them to see and explain why the reading is high.

Now, frequently, in the course of our explanations we may enter into a record, "Well, this particular film badge was left in the X-ray room while the technician was out to lunch--and was exposed accidentally," and that is recorded in the record, then, would this information be usable?

MR. KRONZER: Now, let me see if I can answer that so that each of you can understand--and I want Tom to correct me. To the extent that the entry you speak of appears to have been made by you with knowledge that the badge was out in some employee's room, that part would be receivable because that does record an act, event or an occurrence. But, then, if you draw from that the conclusion, that this is not a true reading, then that's the part that won't come out in court. The record of the act is admissible so that the witnesses or the jury may draw their own conclusions that it's not a true reading, but, not the opinion that therefore, it is not a true reading.

Do you agree with that, Tom?

MR. ALEXANDER: Yes.

MR. KRONZER: The recording of the act, event or condition would be admissible.

MR. ALEXANDER: There is one thing I would like to add on this particular subject:

We are basing our opinion on the present state of the law. The law is a living, growing thing. It grows through courts and it grows through the legislatures. Someday, there may be definite standards established by which we could say that your reading of 30, (I'm just using it for an example)--on your badges of that day is an overdose and is such an obvious overdose that it is analogous to the broken leg situation. That is, it may in the future be such an obvious overdose that no physician could disagree on it.

Our test now for excluding opinions in records, is that if it is an opinion over which physicians could disagree, then, it will not be admitted. However, if it is an opinion over which physicians could not disagree, then, it would be admissible.

And it may be that while there could be considerable disagreement now, in ten years, there may not be. And ten years hence is when the record may be relevant.

Also, there is the possibility that legislative standards may be advanced. Although not directly analogous, this is somewhat analogous, to the now established standard that 0.1 per cent of alcohol in the blood is too drunk to drive a car. And that is a rank opinion, an opinion that I do not share. I don't know about you Jim.

MR. KRONZER: We couldn't, Tom.

MR. ALEXANDER: If we drive slow and kind of keep awake--

MR. KRONZER: We couldn't subscribe to that, Tom.

MR. ALEXANDER: But, nevertheless, it is established now without any question of a doubt, and you can make a criminal case against anybody in this county on that blood test, even where that blood test has been recorded 20 years ago. In fact, the standard has been lowered. It used to be 0.15. But, I guess now that cars will go faster or are more dangerous or whatever, 0.1 is too drunk to drive an automobile. And it may be reduced to 0.075, at which time, a record that is kept now may be rendered admissible later. And that same analogy may be drawn in your field.

DR. GORSON: The problem many of us have is, do we keep records primarily for our own purpose, and having done so, there is this question, "Now, shall we throw them out, or is there some other reason to keep the records." Frequently, we have the question arise of whether they have any legal significance. Now, I personally tend to destroy them after the records are completed and have served my purpose. However, we haven't done this in the case of the film badge records, which could go back for 20 years because the question hasn't been settled. Now, what I'd like to know, from the viewpoint of the lawyer, could we throw away all the records which are more than five years old, having once gone through them again rendering an opinion onto our own records as to what the readings were; that they were all below a certain level and then close the book at that point? From a legal viewpoint, do you think that would be a proper procedure?

MR. KRONZER: Well, as I said earlier--I believe Dean White is right and I believe the essence of what most of you have expressed in your talks is right, that tort law is not capable of dealing with the delayed physical or biogenetic effect of cumulative exposure. We just can't wait that long to get our kiss at the pig. We have no way to embrace that within our concept. And Dean White is right. However, again, basing it on working you all's web of thought through my Teutonic cerebrum, I'm concerned that you all are not yet knowledgeable enough as to what the effect of those exposures may be years hence, either. If that's true, records may have a vitality in this developing field that would commend you not to destroy them. They may be of value in the future at sometime when you all can just say, "It's this way." I realize science is not that way. You all have many ambiguities within the limitations of your concept, too.

DR. CLIFFORD NELSON: I'm wondering about the constitutionality of requiring the keeping of these records. It isn't clear to me whether or not we could get into this matter of requiring physicians to keep records and whether or not it would be a constitutional violation of the individual's rights to require the keeping of these records.

MR. KRONZER: Well, as you know, both the Atomic Energy Act and the state regulations uniformly exclude the physician. Now, of course, if he's got an encapsulated source, that's something else. But, to the extent that either the Federal or the State government, in dealing with radioactive substances, imposes a criminal obligation on the keeping of records of a certain type, that itself is not unconstitutional. And the keeping of them or the failure to keep them properly couldn't be unconstitutional. Whatever the crime would be, either misdemeanor or felony, either one, could be laid against you and--you're just running around the mulberry bush constitutional-wise there. Now, if they were trying to get you on your records or lack of records, you say, "I ain't telling you nothing." That's where the Fifth Amendment comes in. But, only at that level; not at the level where they fine you for not keeping records.

To me, the issue on whether additional or new records should be kept resolves itself this way--to this simplicity: Is it too much of a burden to put all this stuff down and perhaps add another Pentagon Building somewhere to keep it in, when compared to the value it could potentially have from a scientific standpoint?

That's all the question is. And I doubt that we're at that level of proficiency yet.

DR. NORMAN TELLES: I think we all recognize that record material may have some value. I don't know about these other gentlemen, but I have tried a number of these radiation exposure cases from the defense standpoint and as far as I'm concerned, there is absolutely no substitute for adequate and full and complete record material.

There has been quite a bit of talk about the burden of proof. Of course, I recognize where the burden of proof lies in a plaintiff's case and I understand what the rules are with respect to that type of thing in most of the courts. But, in addition to the rules, I think there's also a practical situation concerning what the court and what these boards actually do with cases to be determined.

In the first place, you are normally faced with a situation where the man is dead, leaving a family behind him with no particular income, or he sits there before the Court or before the board and he's on the verge of dying and everyone knows that maybe he's going to die--if it's acute leucocytic leukemia or something of that kind. I think you're quite unwise to approach the situation from the weakness of that particular man's case and what difficulty he's going to have in proving what radiation exposure he has received, because he's not going to know how much he received. He can't see radiation. It's been mentioned here that you can't feel it and you can't hear it. All he knows is he's been working at a job which has a potential for radiation exposure. He comes in and he says that he worked at such and such a place and worked with such and such a material and he doesn't know how much he has been radiated, but he does know that from time to time the health physics people would come in and they would move him out of that area or they would rope off that area or from time to time, something would happen to the system and he would see smoke and he would feel it burning in his nose or something like that.

Now, if you're sitting on the other side of that table and you don't have any records to show how much exposure he had or what kind of materials he's working with or what the characteristics of this material are or precisely what his exposure was and you're planning to sit back and in effect let him try to prove his case, then at the same time you are engaging in that kind of thinking you better be taking a look at your bank account and see what kind of check you're in a position to write. I just know that it doesn't work on that kind of a basis. And with respect to the records I, at least, whether it's right or wrong, get every scrap of record material that I can get. I take not only data on this particular case, but every bit of data they have, whether it's film badges, air environmental data, floor swipes, spot job checks or whatever it may be. I gather everything I can get on the boy, fecal or what-have-you. I get everything that he has done in connection with that operation and any previous operations, including any potential radiation exposure or any therapy he's had. I get people who have the information as to how that data is put together and how these records are kept, and who are able to explain them. I get them to make a calculation and develop this thing. Then, I turn it over to a competent health physicist who can analyze it and can weigh it and can come up with a calculation. I don't care whether you call it an estimate or a calculation or what, it's the best thing we have, and it gives the Court and your radiological health people and your professional health physics people something that they can get their teeth into. And whether you can, from a purely medical standpoint, make a precise causal relationship connection or not, it's the best thing that the Court has. They can't stick their head in the sand. The case is not going away. It has to be decided. And they will decide it, either for you or against you.

To the extent that you don't have the best available information, I think you come up with more ill-advised decisions than we may be having today. With regard to the future peacetime Atomic Energy Commission or the judicial system--the individuals who work in this industry or society in general--I think it's harmful if you don't try to put the information in such form that these people can base judgment upon the best data you have. Whether it's important data or not, that's another question.

MR. ALEXANDER: Let me say about that, first, there's a man that's been there. I can see that. He knows whereof he speaks.

And second, for you people that are in industry and in the insurance industry, you don't have to be there many times to know that where you have a person on one side of the table whom you can't dismiss there with a grin or laugh who really is seriously injured or has left a bunch of children after a death, whether the law books say so or not, the burden of proof is on the corporate defendant sitting on the other side of that table. And if that corporate defendant does not come forward with proof to support his contention of innocence, he might as well, as the gentleman said, get out his checkbook. That's just the way it works. Aside from the legalistic and aside from the niceties of the decisions and the law, the burden lies with the person with access to the information. If they haven't accumulated information or for some reason don't come forward with it, they are in trouble.

MR. KRONZER: Let me only say this: That is true, what the gentleman from the Public Health Service says. And, of course, he is psychologically in the defense role.

But, without regard to that, I don't think we have any misunderstanding about what records are admissible. You are not suggesting to this group that opinions in those records should be received?

DR. TELLES: No. Not at all. I think you've got to lay the foundation for all of this.

MR. KRONZER: To that extent, I think the records would be great. Just as I suggested I don't believe he ought to destroy those records that they have accumulated showing exposure, such as film badges and these pocket dosimeters. But, the interpretation is not admissible evidence at this time in the tort concept.

MR. ALEXANDER: I would agree 100 per cent on the retention of any record material you have, at least until you start getting cluttered with it.

DR. TELLES: The last case that I was involved in was a myelofibrosis case which dealt with an individual who had worked in the electromagnetic section at Oak Ridge in 1944. Suit was brought in 1966. And in 1944, we didn't have the instrumentation, and we didn't have the record and the whole atmosphere was different during World War II. We had a dearth of records. All we had was a man who was on the verge of death--and did die--and really, no way of determining from any record material what his exposure had been.

We virtually had to reconstruct that electromagnetic facility and pull together people from all over the United States who were familiar with that operation, not to prove what he did get, but to prove what he couldn't have gotten.

MR. KRONZER: My understanding is 36 or 37 states have adopted the Model State Regulations and are requiring the very information that you were talking about. And I'm for that. Now, when you get down to dealing with these doctors who are not yet brought within the vortex of those regulations except where they are especially licensed, how much value is it to add to them a requirement to keep this volume of stuff that may never have any true relevancy to any man's problem. Now, that's what I think the issue is, to change the existing requirements.

DR. TELLES: I would agree with the remark that I believe your colleague made.

MR. KRONZER: No. No. That's overstating it.

DR. TELLES: I don't think the record-keeping should be based in the frame of future litigation. I think it should be in the frame of good health physics, good employee protection, and a good, safe operation. Now, if you conduct an operation and you have procedures to carry out those functions and in doing so, you document the individual exposure whether it be therapeutically given with an X-ray machine or whether it's any other exposure, and then, later on, you get involved in litigation, I think you have the record material.

MR. KRONZER: That reaches right to the throat of it. Would you suggest that the present law be amended so as to require the recording of the amount of dosages given--intentionally given--by any person, such as radiologists or any health physicist utilizing radioactive source material?

DR. TELLES: That gets over to the medical field that I have nothing to do with, of course. But, I think it would be a good practice to document that type of thing. If you give a man maybe 1,500 R's to the stomach or something of that kind, I think that's a good record to have. Later on, someone else may want to give him another 1,500 or 3,000, or whatever the figures are. I'm not a health physicist, so I can't talk about these numbers in terms of dosage.

MR. KRONZER: Assuming they might have some potential relevancy, do you think the cumbersomeness of it is outweighed by the potential value? That seems to me to be what you're talking about.

DR. TELLES: Of course it involves a weighing of all of the factors. There comes a time when you have to decide how precise and how detailed and how much time and money this risk reasonably warrants having it done.

DR. COLLINS: It has been a fascinating two days seeing an interfacial reaction between the two disciplines. What we are talking about here is exemplified by the comment that Mr. Kronzer made: "We want your records. We don't want your interpretations." On the other hand, I offer for example, a case I saw about a week ago, It isn't radiation, but it's a problem, just the same. A young man was brought in unconscious. He had a history of being hit on the head with a lead pipe three or four days before.

He had a visible lump there. He was unconscious, and could give no history. There was a cherry red spot on his head. What would you like to have? Do you want my opinion or do you want the lab reports? Do you want the opinion of the radiologist or the skull X rays, the pathologist's opinion or the numerical values for blood chemistry. The question is, does the man have a brain injury or does he have carbon monoxide poisoning? It developed that he slept in a room the night before in which he turned on the gas heater for the first cold spell of the winter. Now, if this is a question of suing the lead pipe company or suing the manufacturer of the gas heater, what evidence would you have? The purpose of the parties to the suit may govern the use of the available evidence. The attitude of the expert witness is one of "Take it or leave it." The evidence, the records, that I need are going to be used differently. He does not really care about the attorney's varying requirements depending upon whether he hopes to recover from the lead pipe company or the manufacturer of the gas appliance. As Dean O'Toole said earlier today, we are divided by the same language. Medicine is concerned with curing the individual's physical ills; the law, with curing his social problems or injustices. Now, this breach should not be and is not going to be resolved completely in the next few years. But, as long as we recognize that you have your rights and your interests in records, we will provide some for it. Well, you understand the position of the physician who comes to court then. He's going to be very unhappy when you doubt his interpretation and want only the records. Perhaps meetings like this are going to bring us a little bit closer together and we'll be a little less antagonized when we come to different views on the same records.

MR. KRONZER: No, Dr. Collins. Like the Marine poster says, "We want you." We don't want the records. We want you down there.

DR. COLLINS: But, see, I don't want to go.

MR. KRONZER: That's right. You don't want to go down there. That's the problem. We don't want the record. We want you. We want your interpretation of whether this is due to monoxide or whether it is due to an injury.

MR. ALEXANDER: What he's saying, Jim, is that at this stage, we are not involved-at this stage, hopefully, there is no disagreement about what the situation is. We don't get involved unless there is a substantial disagreement as to the cause or effect, one of the two. There, at that point, they are not concerned with cause or effect except as it may pertain to medical treatment. And in that regard, they want each other's opinions and they don't want to cross examine each other. In fact, they are very sensitive about it, I've found.

STATUTES OF LIMITATIONS IN TORT CLAIMS: MEDICAL ASPECTS

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In 1944, while Nathan C. Schwartz was in a Naval hospital, a product called "Umbrathor", manufactured by Heyden Newport Chemical Corporation, was inserted into his sinuses for the purpose of making them perceptible in x-rays. Some of the substance allegedly remained in this man's head, resulting in a carcinoma, which required the removal of an eye in 1957. In 1959, Schwartz brought suit in the State of New York against Heyden, alleging, among other things, that Heyden was negligent in certain respects relative to their product and that his injuries were caused by such negligence. A New York statute provided that actions for personal injury must be brought within three years and, on the basis of that statute, a recovery of damages against Heyden was denied despite his assertions in his brief and oral arguments that the carcinogenic qualities of the injection which he received were not discoverable by him until after his 1957 surgery.[1]

Assuming that Mr. Schwartz had no opportunity to discover the insidious and inherently unknowable nature of the cancer produced in his body, one might validly question the propriety of such a result and a brief examination of the basis for statutes of limitations might be appropriate.

Statutes of limitation are creatures of the legislature and substantial differences in the statutes of various jurisdictions can be found. These differences exist not only in relation to the numerous subject matters to which they are addressed but as well to the content of the various statutes within a specific subject matter. An inquiry here is directed only to the field of personal injury and, therefore, we will be concerned only with statutes of limitation relating thereto.

As a general rule, it has been stated that the basic principle most generally relied on by the authorities is that statutes of limitation are statutes of repose, the object of which is to suppress fraudulent and stale claims from springing up at great distances of time and surprising the parties or their representatives when all the proper vouchers and evidences are lost or the facts have become obscure from the lapse of time or the defective memory or death, or removal of witnesses.[2] On its face, this principle appears to operate solely in favor of defendants and would not seem to consider any equities which might exist in favor of a particular plaintiff. In fact, statutes of limitations, in personal injury cases and otherwise, have been held to apply with full force to bar the most meritorious claims and it has been said that courts cannot refuse to give the statute effect merely because it seems to operate harshly in a case involving an obviously meritorious claim.[3]

There are cases which, on their facts, can be justified by the rationale of the general rule. The obvious and usual situation arises when the negligent act and resultant injury are concomitant and of a nature to be known and recognized upon occurrence. Under such circumstances, an injured party should be required to timely bring his action for damages or be forever barred and the justification of a limitation statute can usually be readily accepted in that context. But consider the situation in which Mr. Schwartz found himself where his action for damages was barred before he could have possibly known of the injury he had sustained as a result of the negligent act of another. Medical patients are particularly subject to such inherently unknowable injury caused by their physician's negligence in the event of faulty diagnosis or faulty treatment, not to mention the failure to remove various surgical paraphernalia from an anatomical incision prior to closing it. The same thing is especially true in cases of radiation injuries which, because of their very nature, may not be manifested until long after the applicable statute of limitations had run.

Despite the obvious inequities and hardships of such a result, some courts have denied any recovery of damages for an otherwise meritorious claim by adopting a strict and literal application of the statute by which they feel bound.[4] On the other hand, the distasteful results which obtain in cases where an individual sustains an injury caused by the negligence of another, but the injury is such that he has no opportunity of discovering it until the applicable statutes of limitations have run against him, have caused some courts, when confronted with this type of case, to resort to various exceptions which they feel are justified in avoiding an application of the statute of limitations which would otherwise bar the plaintiff from any remedy.

At the outset, it should be noted that at least seventeen (17) states have enacted statutes of limitations specifically applicable to medical professional responsibility suits.[5] However, such statutes are apparently not necessarily enacted in order to ameliorate any harsh results relating to limitations which might be felt peculiarly present in a plaintiff's malpractice action. To the contrary, some such statutes have provided for a shorter period of limitations in a malpractice action against medical professionals than for other type personal injury actions.[6] In any event, because of the specificity of malpractice statutes, they must be consulted and applied in appropriate type actions.

A substantial number of the state statutes of limitations provide that actions for the recovery of compensation for damages or injury to persons must be instituted within a specific period of time after the cause of action "accrued".[7] Some difficulty has been encountered by various courts in interpreting the moment of time intended by the word "accrued", some courts resolving this problem in a strict and literal manner, usually to a plaintiff's detriment, while other courts prefer to apply a less literal and perhaps more humanistic interpretation thereof in an appropriate situation. Representative of the former type interpretation is that given by the courts of the State of Virginia, the most recent expression thereof being found in the Virginia case of Hawkes v. Dehart,[8] in which the plaintiff sought a recovery for damages caused by a needle left inside her body after surgery. The Virginia statute of limitations provided that every action for personal injuries "shall be brought within two years next after the right to bring the same shall have accrued".[9] Despite the fact that plaintiff asserted that she had brought her action within the statutory period provided therefor from the date on which she first discovered the defendant's negligence, the court ruled that the statute had run when the wrong was done and not when the plaintiff discovered that she had been damaged. Recognizing cases to the contrary fixing events other than the time of the wrongful act as the time when the limitation begins, the Virginia court felt that their position was justified by authorities as reflected in the text from Louisell and Williams "Medical Malpractice", in which it was stated: "By far the majority of courts have held that in the absence of special circumstances that are common to various types of cases, particularly disability of the plaintiff or fraudulent concealment by the defendant, the cause of action accrues and the statute commences to run at the time of the wrongful act. Among the common situations involving this issue are the foreign body cases, i.e., those where the gauze sponge or surgical instrument is left in a patient at the time of surgery. Most cases place the accrual of the cause of action at the closing of the incision, not at the discovery of the fact sometime afterward. The statute usually is held to run from the wrongful act, not the date the damage occurs."[10] It might be noted that the pertinent paragraph quoted from the work of Louisell and Williams has since added the following new text: "Subsequent to publication of the treatise in 1960, there has been substantial decrease in support for the time-of-wrongful-act rule." The added text is certainly a valid observation of the trend apparently being taken by an increasing number of courts which have been faced with this problem in recent times. One court has expressed its refusal to permit the statute of limitations to bar an action such as being considered herein by stating that "Justice cries out that she (plaintiff) fairly be afforded a day in Court".[11]

Yet, there are still instances in which the plaintive cry for justice apparently goes unheeded. Consider the interpretations accorded the applicable statutes of the State of Missouri.[12] Missouri law provided for a two year statute of limitations within which an action for malpractice might be brought. Additionally, and apparently to resolve the type conflict with which other jurisdictions had wrestled, the Missouri legislature prescribed definite criteria for determining the date of accrual of causes of action, including that of malpractice, as follows: "[T]he cause of action shall not be deemed to accrue when the wrong is done or the technical breach of contract or duty occurs, but when the damage resulting therefrom is sustained and is capable of ascertainment, and, if more than one item of damage, then the last item, so that all resulting damage may be recovered, and full and complete relief obtained." This statute was seen to equate to a "discovery" test for fixing the commencement of the running of limitations and would have so equated had subsequent interpretation by the Missouri courts not adopted an objective theory of the meaning of the statutory words "capable of ascertainment" without regard to the possibility of discovery of the injury in question by the injured party.[13] However, the result of the interpretation indicated has been ameliorated by at least one exception in favor of a plaintiff in a malpractice suit to the effect that the statute does not commence until the treatment of the plaintiff's ailment by the physician ceases.[14]

As a matter of fact, the "end of treatment" exception accepted by the Missouri court has also been adopted by other jurisdictions.[15] This doctrine is one that has been rationalized on the basis of the relationship existing between a doctor and his patient. Because of the very nature of this relationship, patients might expectedly be lulled into a degree of complacency, not unusually having placed themselves completely in the hands of their doctor, anticipating full and adequate treatment until such time as their medical difficulties have been completely resolved. As a matter of fact, it would not be unusual to expect that some degree of success in the treatment afforded by the doctor might be validly attributed to the mental set of his patient for, as a practical matter, lack of full and complete confidence in one's physician has been felt to serve as a deterrent to the ultimate result of treatment sought by the doctor. Accepting this reliance on the expertise of the doctor, it would follow that a patient would not readily turn to other medical sources for an independent evaluation of the nature of his physical difficulty and recognition of this attitude on the part of medical patients should serve as justification for the "end of treatment" doctrine. As expressed in *Hundley* v. *St. Francis Hospital*, "[T]he rule is clear, as to malpractice actions, that while the physician-patient relation continues the plaintiff is not ordinarily put on notice of the negligent conduct of the physician upon whose skill, judgment and advice he continues to rely. Thus, in the absence of actual discovery of the negligence, the statute does not commence to run during such period, and this is true even though the condition itself is known to the plaintiff, so long as its negligent cause and its deleterious effect is not discovered.[16]

Two classical "end of treatment" holdings are found in *Borgia* v. *City of New York* and *Lundberg* v. *Bayview Hospital*.[18] In *Borgia*, the negligence complained of was a momentary condition of anoxia (lack of oxygen to the brain) which caused the injury sustained. Apparently, without further negligence, the patient was treated for a period of time thereafter. Suit was brought within the applicable limitation period from the date of the end of treatment of the plaintiff but beyond the date of the alleged negligent act. This court held that "at least when the course of treatment which includes the wrongful acts of omission has run continuously and is related to the same original condition or complaint, the 'accrual' (of the statutes of limitations) comes only at the end of the treatment." Again, in *Lundberg*, a hospital pathologist negligently diagnosed a patient's condition as carcinoma of the cervix and, as a result of such diagnosis, the patient underwent a hysterectomy. The patient was discharged from the hospital in due time but returned thereafter for periodic observation and checkups which was customary and usual procedure in cancer cases. Because of her continued returns to the hospital for the purposes indicated, this patient's relationship with the hospital did not end for a period of almost one year after the date of her discharge. Subsequently, this patient learned of the negligent diagnosis and unnecessary operative procedure and brought suit against the hospital more than two years (the applicable period of limitations) after the negligent diagnosis and surgery but less than two years from the date when her relationship with the hospital ended. Obviously, under the circumstances with existed in this case, the effect of the negligent act was completely visited upon the patient at the time of the surgical procedure to which the patient was subjected. Although she remained an out-patient of the hospital for a period of time thereafter, there were no other acts of negligence, nor any apparent continuing negligence, which could, in and of themselves, have provided a basis for interrupting the applicable period of limitations. Nonetheless, this court took the position that their two year statute of limitations did not begin to run until a medical relationship had finally terminated and, accordingly, ruled against the hospital in this regard.

Another facet of the "continuing treatment" approach is the requirement that such continuing treatment be connected with the original negligent act. This requirement contemplates a situation which might be characterized as a "family doctor" relationship in which the patient routinely returns for treatment of all ailments to the same doctor. Under such circumstances, courts have been reluctant to withhold the running of limitations as long as the patient receives any treatment from her physician for such continuation would appear to be wholly arbitrary and without competent precedent. Accordingly, the "continuing treatment" doctrine has been limited to the shorter period of time during which the patient was under treatment for the condition out of which the medical malpractice arose, which would certainly appear to be consonant with the underlying purpose of this rule.

In practice, the "end of treatment" doctrine has not been applied in a uniform manner by those courts which have adopted this exception to toll the running of statutes of limitation. Distinctions have been made, for instance, where there was continued negligence on the part of the physician, apart from the original act of negligence, such as a failure to remove a foreign object from a patient's body, thus constituting a continuing wrong so long as the patient remained under the defendant's care;[19] where there was a failure to correctly diagnose and treat a condition which was subject to such diagnosis and treatment during the physician-patient relationship;[20] or where the physician improperly treated his patient throughout a continuous course of treatment for the initial ailment.[21]

Another form of relief to an injured party whose claim would otherwise be barred by the statute of limitations has been made available under circumstances characterized as "fraudulent concealment", the effect of which is to toll the statute until the hidden injury has been, or should have been discovered. Indeed, fifteen states have passed statutes specifically tolling the statute for fraudulent concealment.[22] Where this exception has been utilized, the statute would normally be tolled until the patient actually discovers, or should have discovered, the injury which he has sustained as a result of the negligent act or omission.[23] Of course, this exception would have its greatest currency where a doctor is aware of his negligent act and resultant injury but a serious drawback to the plaintiff's case exists in his burden of proving that the doctor had such actual knowledge of his negligence. Assuming ability to prove the necessary facts, all should agree that a physician who is aware of his own negligence and any injury resulting therefrom and who purposely misleads his patient by statements calculated to subdue any doubts which the patient might otherwise have about his physical condition should clearly be guilty of fraudulent concealment, which would toll the running of any statute of limitation. Although some courts have required more than mere silence on the part of a physician before imposing this exception, it has also been held that the relationship between the physician and his patient is a fiduciary one and that, as a fiduciary, it was the duty of the doctor to make a full and fair disclosure to his patient of all facts which materially affected his rights and interests.[24] Another result of the fiduciary relationship is to shield the plaintiff from the obligation of determining for himself the extent or existence of an injury due to malpractice so long as he continues under the care of his doctor.[25] As an example of the antipodal positions taken by various courts relative to fraudulent concealment, some cases deny the availability of such doctrine at all,[26] while others have extended the doctrine to include "constructive fraudulent concealment". This extension has been used to obviate the requirement of scienter normally prerequisite to an allegation of fraud. The basis for this doctrine is not entirely clear and may seem to be utilized by a court in a patent effort to toll an applicable statute of limitations when no other alternative for relief on behalf of a plaintiff appears possible. As in any of the exceptions which are characterized as "fraudulent concealment", the statute is not tolled beyond the time that the plaintiff discovers or should have discovered the negligent injury which he has sustained and, in this view, the so-called "constructive fraud" doctrine appears to be little other than the "discovery doctrine" which will be discussed herein below. If this is so, a better approach to the problem involved would appear to rest with the more honest "discovery doctrine" rather than the application of a fiction such as "constructive fraud".

Another exception to the so-called majority rule which sets the commencement of the statute of limitations at the time that the wrongful act took place is known as the "discovery rule", a rule said to have been first applied in the early case of Hahn v. Claybrook.[27] Its appeal as an equitable approach to the inequities created by strict applications of statutes of limitations in the "inherently unknowalbe" type of injury was not immediately generated. Nonetheless, this doctrine was adopted at a moderate pace by a number of jurisdictions as they were faced with the limitations problem. The need for such a solution had long been recognized, as indicated hereinabove, giving rise to the various exceptions indicated to the "majority rule". It may well be that the decision in Billings v. Sisters of Mercy of Idaho[28] in a well written opinion brought sufficient attention to the discovery doctrine to give it the impetus it needed to gain the approval of an increasing number of jurisdictions as this specific problem has been presented to them. The court in the Billings case acknowledged that the discovery doctrine was a minority rule, such rule arguably having been accepted by only eight or nine jurisdictions prior to that time. However, this court further noted the alternative exceptions which had been applied by various courts and stated that it appeared that most jurisdictions, when faced with the set of facts which were presented to them, would, on one theory or another, allow the aggrieved parties to come into court and present their claims. On this basis, the Billings court stated: "To apply the label of 'general rule' to respondent's position and minority rule to the discovery doctrine is not only misleading but erroneous. If, however, it is necessary to apply labels, it appears that the so-called 'general rule' as stated in A.L.R. [80 A.L.R. 2d 380] is, in fact, the 'minority rule'. In reality, the 'general rule' has little to recommend it. It is neither the position of a majority of the jurisdictions nor is it firmly based on considerations of reason or justice."[29]

Since the Billings decision, the discovery rule has been adopted by an increasing number of jurisdictions.[30] Some of these jurisdictions have applied the discovery rule in situations in which one of the alternative exceptions might have been utilized. Several of these jurisdictions specifically overruled earlier case law to the contrary in adopting this doctrine.[31]

It is suggested, however, that the Billings court unfortunately prescribed a limitation to the discovery rule when it couched its decision, as follows: "We will, therefore, adhere the following rule: where a foreign object is negligently left in a patient's body by a surgeon and the patient is in ignorance of the fact, and consequently of his right of action for malpractice, the cause of action does not accrue until the patient learns of, or in the exercise of reasonable care and diligence should have learned of the presence of such foreign object in his body."[32] This limitation of the discovery rule to "foreign objects" cases was recognized in the subsequent Idaho case of Owens v. White[33] in which the rule was held to be inapplicable. In that case, the plaintiff's complaint was diagnosed as a malignant cancerous growth, as a result of which, she submitted to a radical mastectomy. Twelve years later, this plaintiff was advised by another doctor that she had never been afflicted with cancer and she, accordingly, brought suit against her original physician for negligent diagnosis. The limitation on the discovery rule was justified by a feeling that the purposes of statues of limitations "to prevent fraudulent and stale actions from springing after a great lapse of time" would less likely be frustrated in a foreign object case.[34]

On the other hand, such a limitation on the discovery rule was specifically rejected by the Rhode Island Supreme Court in Wilkinson v. Harrington.[35] In that case, allegedly negligent radiation treatment for a malignant tumor in 1951, was not manifested until 1955, when a small discolored circle appeared on the patient's chest and worsened thereafter, ultimately requiring nine operations involving delicate skin grafting. Carrying the discovery rule still further, the Supreme Court of North Dakota in Iverson v. Lancaster[36] not only adopted the rule but pointed out that under some circumstances, an extension of that rule might be necessary during the continuation of the doctor-patient relationship.[37] Incidentally, the Iverson case involved an erroneous diagnosis which led the plaintiff to submit to a hysterectomy which subsequently proved to be wholly unnecessary.

The distinction that some courts are willing to recognize in "foreign object" cases as opposed to other meritorious claims involving inherently unknowable injuries, such as an undetectable radiation injuries, appears tenuous at best but is indicative of a reluctance to stray very far from the aegis of limitation statutes. An adoption of the discovery rule without the indicated exception would seem to be preferable in dispensing justice to both plaintiffs and defendants, and, of course, a number of courts have adopted such an approach. An intermediate position has also been taken in a few jurisdictions which probably lends an element of unpredictability in a given situation but which is designed to effect maximum protection to both sides of the subject controversy. This intermediate position has been expressed as follows: "This suggests in our estimation, that the discovery doctrine is itself subject to some restraint as the time from the occurrence of the malpractice grows greater. In such circumstances, the considerations of fairness to the defendant underlying statutes of limitation become more insistent, while the plaintiff's appeals to equity implicit in the discovery doctrine become less so. We believe the Idaho courts would apply a concept akin to the equitable doctrine to laches to limit the discovery rule, a rule which itself has its genesis in equity. Thus, the suit of a plaintiff who is reasonably diligent may be barred if the defendant shows undue prejudice because of an extreme lapse of time between the commission of the wrongful act and the commencement of suit. To so conclude strikes us as a reasonable accommodation between the competing considerations noted in Billings of giving full scope to the statute of limitations on the one hand and according a reasonable measure of justice to the plaintiff on the other."

The foregoing review points up the substantial shortcomings presently existing in the application of statutes of limitations in cases involving latent injuries. As indicated, claims for injuries arising out of radiation exposure are subject to the various state statutes which have given rise to completely inconsistent approaches and results in the resolution of these controversies. Some of these cases have visited gross injustices upon meritorious claimants and imminent authority has recognized and made recommendations for statutory revisions leading to consistency of result coupled with fairness to the parties involved. Typical of such recommendations is the suggested state legislation proposed by the Committee of State officials on Suggested State Legislation of the Council of State Governments, as follows:

> "Section 2. Limitation Periods.
>
> No action or proceeding may be brought to recover for an ionizing radiation injury more than three years after the person suffering such injury had knowledge or ought reasonably to have had knowledge of having suffered the injury and of the cause thereof, but in no event more than thirty years from the date of the last occurrence to which the injury is attributed.
>
> Section 3. Latent Injury.
>
> No action or proceeding to recover for latent ionizing radiation damage shall be barred by recovery in any earlier action or proceeding, unless the plaintiff in the earlier action or proceeding shall actually have been awarded damages for the latent injury, or hall have known or reasonably have been expected to know that such latent damage would occur, and its nature and extent with sufficient particularity to establish entitlement to a specific amount of damages on account thereof."

What part can the keeping of records of all radiation exposure play in problems related to statutes of limitations? In the field of tort law, claims for radiation exposure can arise from two primary general sources, i.e., controlled radiation such as received during medical diagnostic and treatment procedures and uncontrolled radiation emanating from unintentional releases thereof due to accident. In the latter event, unknown, and therefore unmeasurable, degrees of radiation might be received according to a victim's proximity, apparel, etc. On the other hand, radiation exposure from medical sources, being controlled, should be measurable and susceptible of recordation. It would seem to follow, then, that record keeping would play its most important role, insofar as statutes of limitations are concerned, in the area of medical malpractice. Furthermore, its value would have to depend in some measure on the general scheme of the limitations statutes themselves.

As can be readily seen, this proposed act, in substance, takes a "discovery rule" approach while incorporating certain limiting provisions, all of which appear to attempt to provide an equitable consideration of the interests affected. Then again, consideration of the availability of centrally kept radiation exposure records might influence the organization and preparation of a uniform statute of limitations.

As the matter now stands, an individual in our highly mobile society may receive a number of diagnostic and treatment procedures over a period of years, not only at the hands of different doctors, but in numberous different localities. He certainly keeps no individual account of such exposures and a doctor he might accuse of malpractice could be sorely prejudiced in defending himself without knowledge of all radiation exposure to which his patient had been subjected. Bearing in mind, that one of the purposes of a statute of limitations is to avoid "fraudulent and stale" claims, the desirability of complete information regarding a malpractice claimant becomes obvious.

Needless to say, the value of such complete records in this regard would rest in no small measure on their validity. Although, on its face, such record keeping might not be justified solely on the basis of benefits that could be derived from their use in connection with statutes of limitations, other considerations touched by such an undertaking will have to be weighed in reaching the decision sought.

REFERENCES

1. Schwartz v. Heyden Newport Chemical Corp., 237 N.Y.X. 2d 714 (1963).

2. 53 C.J.S. Limitations of Actions § 1.

3. Abbott v. Johnston, 195 S.W. 676; Bott v. Equitable Life Assur. Soc. of the United States, 78 P. 2d 860; see also Morgan v. Schlanger, 374 F. 2d 235 (1967).

4. Roybal v. White, 383 P. 2d 250 (1963).

5. Stetler & Moritz, Doctor and Patient and the Law, 390, 391 (4th ed. 1962).

6. e.g. compare Mo. Ann. Code art. 516.120 with Mo. Ann. Code art. 516.140.

7. Hawks v. DeHart, 206 Va. 810, 146 S.E. 2d 187 (1966); Yoshizaki v. Hilo Hospital, 433 P. 2d 220 (1967).

8. 206 Va. 810, 146 S.E. 2d 187 (1966).

9. Id., 146 S.E. 2d at 189.

10. Lovisell & William Medical Malpractice, Sec. 1306, at p. 369 (1960).

11. Fernandi v. Strully, 35 N.J. 434, 451, 173 A.2d 277, 286 (1961).

12. See note 6 supra and Mo. Ann. Code art. 516.100.

13. Allison v. Missouri Power & Light Co., 59 S.W. 2d 771 (1933); see 33 Missouri Law Review 171, 188.

14. Thatcher v. Detar, 173 S.W. 2d 760 (1943).

15. Annot., 80 A.L.R. 2d 368, 379.

16. 161 Cal. App. 2d 800, 327 P. 2d 131, 135 (1958).

17. 17 N.Y. 2d 151, 187 N.E. 2d 777 (1962).

18. 175 Ohio St. 199, 191 N.E. 2d 821 (1963).

19. Waldman v. Rohrbaugh, 241 Md. 137, 215 A. 2d 825 (1966); Frazor v. Osborne 414 S.W. 2d 118 (1966).

20. Golia v. Health Ins. Plan, 197 N.Y.S. 2d 735, 165 N.E. 2d 578.

21. Hammer v. Rosen, 198 N.Y.S. 2d 65, 165 N.E. 2d 756.

22. Lovisell & Williams Medical Malpractice, Sec. 13.11.

23. Rahn v. United States, 222 F. Supp. 775 (1963); See also Dawson, Fraudulent Concealment and Statutes of Limitations, 31 Mich. L. Rev. 875 (1933).

24. Bowman v. McPheeters, 176 P. 2d 745 (1947); Garlock v. Cole, 18 Cal. Rptr. 393, 396 (1962).

25. Morrison v. Acton, 68 Ariz. 27, 198 P. 2d 590 (1948); Adams v. Ison, 249 S.W. 2d 791 (1952).

26. e.g. Rosanne v. Singer, 112 Colo. 363, 149 P. 2d 372 (1944).

27. 100 A 83 (1917).

28. 389 P. 2d 224 (1964).

29. Id at 232.

30. 80 A.L.R. 2d 368, 387.

31 e.g. Gaddis v. Smith, 417 S.W. 2d 577 (Tex. 1967); Yoshizaki v. Hilo Hospital, supra N. 7; Berry v. Branner 421 P. 2d 996 (1966).

32. Supra N. 28 at 232.

33. 380 F. 2d 310 (1967).

34. Owens v. White, 380 F. 2d 310, 315 (1967).

35. 243 A. 2d 745 (1968).

36. 158 N.W. 2d 507 (1968)

37. Id at 512.

STATUTES OF LIMITATIONS IN COMPENSATION CLAIMS

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During the past decade vast attention has been given to the subject of compensation for radiation injuries. Repeated Congressional hearings have been held. Numerous conferences have been convoked. A great deal of legislation has been introduced and enacted. Much of it has dealt with the subject of time limitations.

Time limits for making workmen's compensation claims are of particular importance with respect to radiation injuries. In these cases the manifestations of the effects of radiation may be delayed. It is necessary that statutes of limitations operate fairly with respect to such claims. It is the purpose of this paper to examine and evaluate these provisions.

Originally, workmen's compensation laws were enacted to provide compensation and medical care for traumatic injuries suffered in the employment. Usually these laws covered accidental injuries or injuries by accident "arising out of and in the course of employment." This language or language similar to it is still found in most of the workmen's compensation laws in effect today in this country.

In a number of states, what constitutes an accident has received very broad interpretation. For example, in one state silicosis was held compensable as an accidental injury - In re Pero, Wyoming (1935) 52 P. 2d 690, as well as dermatitis- Wright v. Wyoming Training School (1953) 255 P. 2d 211. In other cases it was felt that the unexpected contraction of a disease was sufficient to satisfy the requirement that the injury be accidental, conjunctivitis from exposure to soot for 4 or 5 weeks- Downey v. Kansas City Gas Co. Mo. Sup. Ct. (1936) 92 SW 580, tuberculosis aggravated by exposure to silica dust-Beaver v. Morrison - Knudsen Co. Idaho 41 P. 2d 605, 97 A.L.R. 1399. Usually, however, an accident was defined as a sudden unexpected event relatively definite as to time and place - Lerner v. Rump Bros. N.Y. Ct. of App. (1925) 241 N.Y. 153, 149 N.E. 334.

The question of what constitutes an accident could easily be the subject of a paper in itself. For our purposes here today it would appear sufficient to state that in all states an accidental injury due to radiation is compensable. This would include cases of unexpected exposure due to some mishap. Probably in such accidents exposure might be fairly heavy and symptoms quick to appear. Time limitations should present no serious problems in such cases.

The usual time limit for accidental injuries begins to run either from the date of injury or the date of accident. In approximately 28 jurisdictions, period in which to make an initial claim is one year and in 18 jurisdictions, two years.[1] In one jurisdiction, Nevada,[2] it is 90 days and in two jurisdictions, Texas[3] and Vermont,[4] six months; in Pennsylvania,[5] 16 months. Usually any question as to limits must be raised at the first hearing and in some cases late filing can be excused. A number of cases[6] hold that, in the event of latent injury, time limits begin to run from the date of such disability.

In addition to specifying time limits for the making of claims for accidental injuries, workmen's compensation laws usually also require the employee to notify his employer of the occurence of the accident or injury. This is necessary so that the employer can make certain that proper medical care is provided and the payment of compensation begun. Usually the time limit within which such notice must be given is relatively brief, but in practically all states failure to give notice is excusable, or notice need not be given, if the employer has knowledge of the accident or injury[7]. It is most probable that in the event of accidental radiation exposure the employer would have prompt knowledge of the occurence.

However, with respect to radiation injuries from extended exposure and latent results it is more probable that the claim would be classified as an occupational disease. Most workmen's compensation laws have special provisions relating thereto. All states now provide compensation for radiation as occupational diseases, Alabama[8] and Wyoming[9] having enacted specific provisions last year (1967).

I have mentioned that originally workmen's compensation laws were intended to cover traumatic injuries. However, it became apparent before long that disability due to disease contracted because of exposure to toxic substances in the employment should also be compensated. As a matter of fact, the Massachusetts workmen's compensation law when originally enacted referred to the term "injury" rather than "accidental injury." That term was gradually interpretated to include broad occupational disease coverage [10]. On the other hand, in Michigan, although similar language was used, the courts for may years held that only accidental injuries were covered[11]. Among the first specific enactments relating to occupational diseases were those in Connecticut[12] and Wisconsin in 1919[13].

Occupational disease laws today provide broad coverage under a definition of general scope. These are found in 34 jurisdictions. In 19 jurisdictions the compensable occupational diseases are listed in a schedule. All of these include radiation injuries in some form (see Appendix A).

There was considerable discussion and debate over the years as to the nature of provisions covering disease. Industry felt it should be held responsible only for diseases that were truly occupational. They feared that attempt would be made to relate to employment in some manner all types of ordinary diseases of life where their relationship to employment was quite questionable. This is particularly true about disability which manifested itself many years after employment and exposure terminated. In many laws, therefore, provisions were inserted in which disability or death, to be compensable, was required to occur within a specified time after exposure.

Such provisions could be a bar to compensation for disability or death, due to radiation exposure, which occurred after the time specified had expired[14]. However, courts have been liberal in circumventing provisions of this type. For example, in one radiation case it was held that the time limitation was not applicable because the exposure was accidental and the claim did not constitute one for occupational disease[15]. Nevertheless, it was recognized, when it became generally known that effects of radiation might be long-delayed, that these provisions should be modified. My good friend the late Ashley St. Clair in a paper[16] presented in 1958 listed 30 jurisdictions having such provisions. I know that in our Association we then became concerned over this matter and, together with mutual companies, strongly advocated amendment of laws in this respect. In 1959 the Joint Committee on Atomic Energy of the Congress held extensive hearings on the subject of compensation for radiation injuries in which the problem of time limits was emphasized.

It is most gratifying now to find that of the 30 states only two, Delaware and Pennsylvania, have not yet enacted legislation on this subject. As a matter of fact, such legislation was passed by the legislature in Delaware[17] in 1962 but this was vetoed by the Governor since the bill was defective in that it ammended only one limitation provision and not another one, thus creating an ambiguity. As a matter of fact, compensation radiation injuries have received very concentrated legislative attention throughout the country since 1959. Over 135 bills were introduced, of which 64 became law. This is a remarkable record of legislative activity.

Most of these laws eliminated completely, with respect to radiation injuries, time limitations related to exposure (see Appendix B). A few of the states retain this provision but greatly extended the period. In Illinois it is 15 years after exposure; in Kentucky and New Mexico, 10 years and in Ohio, 8 years.

In Delaware claim must be filed within 5 years after exposure and in Pennsylvania disability or death must occur within 4 years. Revision of the workmen's compensation law in that state is presently under study and I am hopeful that a change in this respect will be made in Pennsylvania. The law in West Virginia is not completely clear and possibly should be clarified. In Alabama under the recent enactment a three-year period is provided. These are the states where time limitations related to exposure still exist (see Appendix C).

There are, of course, other provisions with respect to occupational diseases specifically describing the time in which claim must be made. In some 32 states, with respect to radiation injuries as occupational disease, time limitation does not begin to run until the employee knew or should have known of the disability and its relationship to his employment (see Appendix B). Provisions of this type are preferable since knowledge as well as the date of disability is taken into consideration.

In most of the other jurisdictions time limitations run from the date of disability or death. These are the same provisions that apply to occupational disease claims generally.

Some have argued that knowledge is essential in computing periods of limitations in making claims for radiation injuries. While such a provision is preferable, a statute of limitations running from the date of disability at least gives the employee time to make a claim after disability occurs. This may be contrasted with statutes of limitations related to exposure which arbitrarily bar the claim when disability occurs after the period has expired. In one state, Colorado, in radiation cases there is a three-year statute of limitations after the disability occurs. I would consider such a statute more liberal than one that restricts the making of a claim to 90 days after the employee knew or should have known of the relationship of the disability to his employment. It might well be contended that a year after the date of disability should be a sufficient time within which to determine relationship to employment and thus claim would be barred by a 90-day "should have known" provision.

In many states the courts have indicated that time limitations do not begin to run in latent cases until a knowledge of disability and its relationship to the employment exists. For example, the court in one case held: "So long as an employee has no actual knowledge that his incapacity is due to an occupational disease, and so long as a reasonable man would not have been on actual notice, then the incapacity could not be said to result from an occupational disease within the meaning of the Act; and the statute of limitations will not commence to run until such notice is present." No reasonable construction of the law could require the complainant, the court said, to give notice of disability which he did not know existed and which did not in fact exist, or that he should file suit for a disability before he had suffered it. This was a claim for silicosis which was held timely. For two years the claimant had known he had pneumoconiosis. The statute of limitations was one year. He filed his claim 16 days after diagnosis that he had silicosis, a specific type of pneumoconiosis and after actual disablement (Wilson v. Van Buren County, Tenn. (1945) 268 S.W. 2d 363). I have appended to this paper a number of references to additional similar decisions (Appendix D).

In some states time limitations run from the time of manifestation of the disease. It has been held that knowledge of causal relationship was necessary to such "manifestation". The court stated "Manifestly, knowledge of the diagnosis but without knowledge or reasonable information that his disease was related to his employment and within the purview of the Workmen's Compensation Act could not enable plaintiff to avail himself of the rights granted under the Act. We are thus of the opinion that the claim had not "manifested itself" within the Act until, in July of 1953, he first became aware the disease was related to his employment." Compensation, however, in this case for blastomycosis was denied since the court felt the claimant had not overcome a presumption against causal relationship due to limited time of employment. There was considerable evidence that his condition was unrelated to the work and he had initially collected benefits for a non-occupational condition (Frisby v. International Paper Co. La. Ct of App. 2d Cir. (1954) 74 So. 2d 621).

As in the case of accidental injuries, in addition to provisions relating to the making of a claim there are provisions for giving notice of the occupational disease to the employer. Frequently these run from the date of the first distinct manifestation of the disease, others from the date of disablement. Many of the laws requiring knowledge are also made applicable to the notice provisions. Usually notice, as in accidental cases, can be excused or is not necessary if the employer has knowledge. However, it is desirable when remedial legislation is being proposed to make certain that any possible difficulties with respect to notice are eliminated.

It is necessary, of course, that remedial legislation be properly drawn. In two states, Iowa and Texas (see Appendix B), in an endeavor to eliminate time limits related to exposure the occurrence of disability has been related to knowledge. While such a provision is better than one related to exposure, disability is not necessarily related to it. It may well be, however, in such cases, that knowledge would not be acquired until after disability had occurred.

Recently, legislation has been enacted in several states extending time limitations with respect to actions at law for injuries due to radiation. While these are apparently intended to apply only to torts, the language used is quite broad and may possibly be held to apply to compensation cases as well. One of these, for example, provides no cause of action may be brought to recover for ionizing radiation injury more than 3 years after knowledge of having suffered the injury and the cause thereof, but in no event more than 30 years from date of last occurrence to which the injury is attributable. In that state, Idaho, all time limits with respect to compensable radiation injuries had been eliminated. This law may again raise some limitation questions (Idaho, S.B. 133 laws of 1967).

I have cited few cases related to radiation exposure. The reason is that there have been relatively few such cases. This is particularly true insofar as court decisions are concerned. The cases that have occurred, as pointed out by Prof. O'Toole[18], have usually been limited to administrative decision. In his 1965 study he found only 109 delayed injury cases had occurred from radiation exposure. This included one Canadian province, Ontario, and the federal government. As a matter of fact, most of the claims, 57, were made under the Federal Employees' Compensation Act. Under that Act no court appeals are permitted, administrative decisions being final. That Act had a very limited statute of limitations, 60 days after injury. This has been amended to provide the period of limitations in cases of latent disability due to radiation or other cause will not begin to run until the employee knows or should have known the causal relationship between his disability and his employment. In death cases the period of limitations is one year (see Appendix B).

Prof. O'Toole states[18] that in only 7 of these cases was the question of the statute of limitations raised and in only 4 cases was the claim defeated on this ground. Two of these were under the federal act which has since been amended. These claims were denied not only because of the statute of limitations but for lack of causal relationship. One was for dermatitis, where the claimant had worked on planes which had been used in Pacific atomic tests. The other was for gastric reaction and stomach ulcer 9 years after accidental spilling of radium in a classroom. Breath samples and blood count shortly after exposure had been normal.

In one Colorado case involving a uranium miner the statute has since been amended. In the last case, in California, the claimant knew of his exposure and disease, thought they were related, but for some reason did not file a claim.

There since have been additional cases due to exposure in uranium mines. As of last June the question of limitation had arisen in three more cases. In one of these I believe the claim could have been upheld if appeal to the courts had been taken. In this case the statute of limitations had been extended before it had expired. In another, the defense of the statute of limitations was not allowed. The third is pending on appeal. The question of limitations would not have arisen under the statute in effect today in that state.

I have attempted to indicate time limitations which may be of importance in relation to radiation injuries. A detailed summary of many of these provisions is appended, together with references to pertinent decisions. In nearly all states these problems have been minimized or completely eliminated by appropriate legislation. Where problems still exist, further legislative action is urged. Care should be exercised in drafting remedial legislation to make certain that proper remedy is actually provided.

REFERENCES

1. Topic 10 - Notice of Injury and Claim for Compensation; Digest of Workmen's Compensation Laws of the United States and Territories, Annotated 16th Edition (permanent loose leaf) American Insurance Association N.Y., N.Y.

2. Claim must be filed with Commission 90 days after happening of accident or one year after death, sec. 616.500, Nevada Industrial Insurance Act.

3. Claim must be made within six months after the occurrence of the injury or the first distinct manifestation of an occupational disease or six months after death or removal of incapacity. Board may in meritorious cases waive strict compliance - Texas Workmen's Compensation Law Part 2, Article 8307, sec. 4a.

4. Claim must be made within 6 months after injury or death unless payment is made voluntarily within that time sec. 656. Want or delay in making claim no bar to proceedings if shown employer had knowledge of accident or that employer has not been prejudiced §660 Vermont Workmen's Compensation Act.

5. Claim must be made within 16 months after accident or death unless agreement made within that time or within 16 months of last payment, sec. 315 Pennsylvania Workmen's Compensation Law.

6. T. J. Moss Tie and Timber Co. v. Martin Ark. Sup. Ct. (1952) 247 S.W. 2d 198; Ford v. American Brake Shoe Co. Mo. St. Louis Ct. of App. (1952) 252 S.W. 2d 649. In fixing time of injury the limitation period begins to run whenever it becomes reasonably discoverable and apparent that a compensable injury has been sustained.

7. See reference 1.

8. Article 2-B, Alabama Workmen's Compensation Law as added by Act 521, Laws of 1967, effective Sept. 7, 1967.

9. Section 27-49, III (a) of the Wyoming Workmen's Compensation Law as added by Chapter 55, Laws of 1967, effective July 1, 1967.

10. Loss of sight from coal tar gases - Hurle's Case (1914) 104 N.E. 336; pneumoconiosis (silicosis) Sullivan's Case (1929) 164 N.E. 457.

11. Adams v. ------ (1914) Mich. 148 N.W. 405; Twork v. ----- (1936) 266 N.W. 211.

12. Connecticut, Chapter 142, Public Acts 1919.

13. Wisconsin, Chapter 457, Laws of 1919 and amended by Chapter 668, Laws of 1919 effective July 30, 1919.

14. Vegliante v. New Haven Clock Co., Conn. Sup. Ct. of Errors, (1956) 143 Conn. 571, 124 A. 2d 526, statute has since been amended to eliminate provision for making claim within 3 years of leaving employment, sec. 31-168 Connecticut Workmen's Compensation Act as amended by Public Act 580, Laws of 1959 effective Oct. 1, 1959.

15. The Incidence, Nature and Adjudication of Workmen's Compensatio Claims involving Radiation Exposure and Delayed Injury by Thomas J. O'Toole. Studies in Workmen's Compensation and Radiation Injury Vol. 11, U.S. Department of Labor and Automic Energy Commission.

16. What Protection Do Our Present Day Workmen's Compensation Laws Afford Workers and their Families Against Wage Loss for Disability or Death from Occupational Diseases? Ashley St. Clair, Proceedings IAIABC 1958, P. 69, U.S. Department of Labor Bulletin 201

17. H.B. 510 Delaware, Regular Session 1962

18. See reference 15.

APPENDIX A

Appreciation is expressed for the assistance provided by my associate Mr. Abraham Farkas in preparing these appendices.

COMPENSATION FOR RADIATION INJURIES

Accidents: All states provide compensation for radiation injuries which constitute "accidents." In many states very broad interpretation has been given to the term "accident."

Broad Occupational Disease Coverage: 38 jurisdictions provide broad occupational disease coverage which includes injuries resulting from exposure to radiation as follows:

Alaska
Arkansas*
California
Connecticut
Delaware
District of Columbia
Florida
Hawaii
Illinois
Indiana
Kentucky
Maine
Maryland
Massachusetts
Michigan
Minnesota
Mississippi
Missouri
Montana**
Nebraska
Nevada
New Hampshire
New Jersey
New York
North Dakota
Ohio
Oregon
Pennsylvania
Puerto Rico
Rhode Island
South Carolina
Tennessee**
Utah
Virginia***
Washington
West Virginia
Wisconsin
Longshoremen's & Harborworkers' Act

* In Arkansas there is a schedule which includes radiation injuries and to which the Industrial Commission is permitted to add diseases to be compensated. A court decision apparently indicates compensation is not limited to scheduled diseases. (Solid Steel Scissors Co. vs. Kennedy (1943) 171 SW 2d 929)

** In Montana and Tennessee broad coverage may be elected.

*** In Virginia, the employer may reject the broad coverage and elect schedule coverage.

Scheduled Occupational Disease Coverage: 15 jurisdictions provide compensation for radiation injuries in their occupational disease schedules as follows:

Alabama - Disability or death due to occupational exposure to radiation.

Arizona - Radiation illness. For the purposes of this chapter, "radiation illness" means physical or mental harm, including but not limited to disease, infection, or pathological changes to an employee arising out of exposure in his employment to ionizing radiation. "Ionizing radiation" means gamma rays and x-rays, alpha and beta particles, high speed electrons, neutrons, protons and other nuclear particles, but not sound or radio waves, or visible, infrared, or ultraviolet light.

Colorado - Poisonings or disease caused by exposure to radioactive materials, substances or machines or fissionable materials.

Georgia - Disease condition caused by exposure to x-rays or radioactive substances.

Idaho - Radium poisoning by or disability due to radioactive properties of substances or to roentgen rays (x-rays) in any occupation involving direct contact therewith, handling thereof or exposure thereto.

Iowa - Disability due to overexposure to radiation from radioactive materials (including radium) and machine produced ionizing radiation (includes x-ray machines) from any process involving use of or direct contact with radium, radioisotopes, roentgen rays (x-rays) or other ionizing radiation.

Kansas - Similar to Georgia.

Louisiana - Similar to Georgia - also has reference broadly to metals other than lead and their compounds.

New Mexico - Contains a provision similar to Colorado - In addition, another specifying that the terms of this Act shall apply to all other diseases contracted by virtue of work connected with and directly traceable to fissionable materials or radioactive materials and not specifically listed therein.

North Carolina - Radium posioning or disability or death due to radioactive substances, x-ray or ionizing radiation (§97-53(17)).

Oklahoma - A provision similar to that in Georgia plus a reference to known diseases contracted by virtue of work connected with and directly traceable to fissionable materials or radioactive materials and not specifically listed herein.

South Dakota - Ulceration of skin or destruction of tissue due to the prolonged exposure to roentgen rays or radium emanations.

Texas - Similar to Georgia.

Vermont - Similar to Georgia.

Wyoming - Injury due to ionizing radiation.

APPENDIX B

TIME LIMITS - COMPENSATION FOR RADIATION INJURIES

Limitations Not Related to Exposure

Alaska: Latent disease cases time for filing claim within Board's discretion, despite time limits; otherwise, 2 years after injury or death. (§12(1).

Arizona: Claim for radiation illness shall be filed within 1 year after disability and time employee knows or by exercise of reasonable diligence should know existence of disability and its possible relationship to employment. In case of death claim must be filed 6 months after claimant knows or should know possible relation of death to employment Sec. 23-1224. Sec. 23-1107 amended to exempt radiation cases from time limitations related to employment, Chapter 6, H.B. 1, 28th Legislature, 4th Special Session 1968, effective Jan. 1, 1969.

Arkansas: Radiation claim must be filed within 2 years after condition is made known to employee by diagnosis of a physician (§§81-1314, 81-1318).*

California: 1 year of injury or last payment of medical benefit. Death, within 1 year of death or last payment but not more than 240 weeks from injury (5405 - 5407). Date of injury in cases of occupational disease is that date upon which employee first suffered disability there from and either knew or in the exercise of reasonable diligence should have known that the disability was caused by his present or prior employment (§ 5412).

Colorado: 3 years after disability or death but no limit if compensation paid (§81-18-11).

Connecticut: 1 year after first manifestation or if death ensues within 2 years thereafter, 1 year after death (31-294).

District of Columbia: 1 year of injury, death or last payment (§13) Failure of employer to file report tolls statute (§ 30f).

Florida: 2 years of injury or death or last payment or treatment, but death must occur within 350 weeks of exposure (§ 440.19).

Georgia: Disability or death due to radiation, claim must be filed within 1 year after claimant knew or should have known caused by employment; otherwise, it must occur within 1 year after exposure, 7 years for death if it occurs after continuous disability for which timely claim is made. (§ 114-801).*

Hawaii: 2 years after knowledge that injury or disease was caused by employment, Sec. 97-91.

Idaho: 1 year after disability or death and knew that it was caused by his employment (§ 72-1228).

Indiana: Disability must occur within 2 years after employee knew or should have known of disease and its causal relation, death 2 years after disablement. (§ 40-2205(e)).*

Iowa: Disability or death due to radiation excepted from requirement that it must occur within 2 years after exposure. (§85A.12). Radiation injuries covered as occupational diseases. (§ 85A.9).*

Kansas: Radiation claim for disability or death must be filed within 1 year after disability and employee knew or should have known it was caused by employment (§ 44-5a17).*

Louisiana: 4 months from contraction or first manifestation. Death, six months after death. Sec. 23:1031.1 (C) (D). Death must occur within 2 years of accident (§ 23:1209).

Maine: Disability or death must occur within 1 year, death 7 years if it follows continuous disability for which timely claim is made, Sec. 189. Radiation claims time limit for disability (1 year) does not begin to run until employee knew or should have known of causal relationship of his disability. (§ 195).

Maryland: Radiation claim for disability or death must be filed within 2 years thereof or claimants' first knowledge that it was due to ionizing radiation (§39(a)&(b)).

Massachusetts: 6 months after injury or death. Delay may be excused for reasonable cause, sec. 41.

Michigan: 6 months after injury or death or cessation of physical or mental incapacity. If employer has notice of knowledge of injury within 3 months after happening, but disability does not develop within 6 months after injury, claim may be made within 3 months after date of disability, but not more than 3 years after injury is sustained. Part II, Sec. 15.

Minnesota: Notice and claim must be made within 2 years after employee's knowledge of the cause and disability (§ 176.151(4)). Disablement must occur within 12 months of contraction, Sec. 176.66.*

Mississippi: 2 years after disability or death (§6998-18).

Missouri: 1 year after injury or death or last payment. (§ 287.020(4)).

Montana: Claim must be filed within 30 days after notice of disability or death after claimant knew or should have known of cause and relation to employment (§§92-1311-92-1313).

Nebraska: Claim must be filed within 6 months after injury or death (§48-133).

Nevada: Claim must be filed within 4 months after disability or 6 months after death, (§ 617.430). Radiation injuries excepted from provision relating to contraction of disease (§617.44C).

New Hampshire: Notice must be given within 1 year after disability or death after employee knows or should have known nature of disease and relation to employment (§281:17).

New Jersey: Claims for radiation poisoning as an occupational disease must be filed within 1 year after employee knew or ought to have known the nature of the disability and its relation to his employment. (§ 34:15-34).

New York: In cases of latent diseases, including those due to radiation, 90 days after knowledge of causal relationship, otherwise 2 years. As to death from latent disease, if no claim for prior disability, it must occur within 5 years of contraction, except for radiation injuries, Sec. 40.

North Carolina: Radiation claims for disability or death, within 1 year after employee knows or should have known caused by employment (§ 97-58). Other cases, one year after disability or death. Death must occur within 2 years of accident or 6 years if it follows continuous disability. (§§ 97-53, 97-58, 97-24, 97-38).

North Dakota: 60 days after injury or death. Death must occur within 6 years of injury and 1 year of cessation of disability, if no disability 1 year of injury. Sec. 65-0501, 65-0516.

Oklahoma: Radiation cases, 1 year after last exposure or disease manifestation diagnosed by doctor, Sec. 43.

Oregon: Radiation cases, 7 years after exposure and 180 days after disability or doctor advises claimant is suffering from an occupational disease, whichever is later, Sec. 656.807.

Puerto Rico: Disability must occur within 1 year of contraction, death within 3 years of accident, Sec. 3. Radiation claims excepted, may be filed 3 years after employee knew or should have known of disability's relation to his work.

Rhode Island: 2 years after disablement or death. In latent cases time does not begin to run until claimant knew or should have known of impairment and causality or after disability, but if benefits were paid, no time limit.

South Carolina: Radiation claim must be filed within 1 year after disablement or death (§§72-303, 72-253, 72-256). Other diseases must be contracted within 1 year after exposure, pulmonary disease 2 years. Death must occur within 2 years, 6 years if follows continuous disability, after accident (§ 72-180). Radiation injuries excepted from contraction provision (§ 72-256).

South Carolina: Radiation claim must be filed within 1 year after accident or death. (§ 72-303, 72-256). Other diseases must be contracted within 1 year after exposure, pulmonary disease 2 years. Death must occur within 2 years, 6 years if follows continuous disability, after accident. (§72-180).

South Dakota: Radiation claims for disability or death, within 1 year after disability and employee knew or should have known that it was caused by his employment (§§ 64-0807, 64-0818).

Tennessee: 1 year of disablement or death, but if disability suit is barred at time of death that of dependents is also barred, Sec. 50-1108.

Texas: Claim must be made within 6 months after occurrence of injury or the first distinct manifestation of an occupational disease or 6 months after death or removal of incapacity. Board may in meritorious cases waive strict compliance (Part 2, Article 8307, 4A). Art. 8306 A also contains ambiguous reference which appears to relate incapacity to knowledge of causal relationship in radiation cases.

Utah: Radiation claims for disability or death, within 1 year after disability and employee knew or should have known that it was caused by his employment (§ 35-2-13 (a) (2)).

Virginia: Radiation cases excepted from limits of 1 year after diagnosis is communicated to employee or death, or 5 years after last injurious exposure, whichever first occurs. Death must occur within 1 year of manifestation or diagnosis. Sec. 65-49.

Vermont: Radiation claims for disability or death, within 1 year after the employee knew or should have known that the disability was caused by his employment (§ 1006 (b)).

Washington: 1 year from notice by physician of occupational disease Sec. 51.08.055.

Wisconsin: No time for injury or death in radiation cases (§ 102.17(4)). Other cases, claim must be filed within 2 years after injury or death and employee knew or should have known of its relation to employment (102.12)

Wyoming: Ionizing radiation claims must be filed within 1 year after injury or employee's discovery thereof (§ 27-105).

Longshoremen's and Harborworkers' Act: 1 year of injury or last payment (§13f). Failure of employer to file report tolls statute (§30f).

Federal Employees' Compensation Act: 1 year after death, 60 days after injury but in latent disability time does not begin to run until disability and employee is aware, or by exercise of reasonable diligence should have been aware of causal relationship. Secretary may waive compliance for good cause up to 5 years after injury or death (§ 8122, U.S.C.A. Title 5).

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*Special provisions for pulmonary dust diseases.

APPENDIX C

TIME WITHIN WHICH DISABILITY OR DEATH MUST OCCUR AFTER EXPOSURE

Alabama: Disability due to ionizing exposure must occur within 3 years after exposure. Claim must be filed within 1 year after disability or death and employee's knowledge of causation, Art. 2-B, 10.

Delaware: Disability must occur within 5 months, Sec. 2301 and claim filed within 5 years, 2361.

Illinois: Disability must occur within 1 year in ordinary cases, 15 years for atomic radiation, 3 years for berylliosis, Sec. 1 (f).*

Kentucky: Claim must be filed within 1 year after exposure, or distinct manifestation in disability cases, whichever last occurs, but within 10 years of last injurious exposure, Sec. 342.316 (3). In death cases, one year after death. Death must occur within 1 year of exposure, distinct manifestation or if it follows continuous disability for which timely claim was made, 10 years, 342.316 (3) (5).

New Mexico: Disability or death must occur within 10 years of last injurious employment against whom claim is made. Sec. 59-1110.

Ohio: Disease must have been contracted within 12 months prior to disablement. Death must result within 2 years of injury or follow continuous disability or compensation. Radiation illness or berylliosis: disability or death (except death following continuous compensable disability) must occur within 8 years after last injurious exposure. Claim must be made for radiation illness, one year after disability began or 6 months after diagnosis, 6 months after death. 4123.68 V, Y, 4123.85 .

Pennsylvania: Disability or death must occur within 4 years, Sec. 301.*

West Virginia: Claim must be made within 3 years of last exposure or 1 year from death, Sec. 23-4-15.

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*Special provisions for pulmonary dust diseases.

APPENDIX D

PARTIAL LISTING OF DECISIONS RELATING TO TIME LIMITATIONS IN LATENT INJURY CASES

Alabama: Late filing permitted where stroke incapacitated employee - Southern Cotton Oil Co. v. Wynn (1957) Sup. Ct. 96 So. 2d 159.

Arizona: Where injury is trivial at time of accident and not compensable but later there develop unexpected results, time limit runs from date injury becomes manifest - Hughes v. Ind. Com. (1956) Sup. Ct. 304 P. 2d 1066.

Arkansas: Time of injury to run statute means time when disabling consequences become apparent or discoverable - T.J. Moss Tie and Timber Co. v. Martin (1952) Sup. Ct. 247 S.W. 2d 198.

California: Time when accumulated effects culminate in a disability traceable to latent disease as primary cause - Marsh v. Ind.Acc.Com. (1933) 18 P. 2d 933; Pacific Indemnity Co. v. Ind. Acc. Com. (1950) 214 P. 2d 530, T.B. of flight instructor.

District of Columbia: Claim for latent injury filed within 1 year of discovery held timely - Knopp v ---- (1934) 8F Sup. 290.

Florida: Time for presentation of claim begins when claimant incapacitated not when it became apparent, dermatitis - Wolfe v. Neal (1963) Sup. Ct. 156 So. 2d 513.

Georgia: Where employee becomes unable to work but presence of silicosis is undetected time runs from earliest time silicosis can be detected as cause of disability - Free v. Assoc. Ind. Corp. (1949) Ct. of App. 52 S.E. 2d 325, 78 Ga. App. 839.

Indiana: Where disablement does not occur simultaneously with accident claim must be filed within 2 years after resulting injury develops or becomes apparent Int. Detrola Corp. v. Hoffman (1947) Sup. Ct. 70 N.W. 2d 844.

Iowa: Occurrence of injury for purpose of time limit relating to notice when physician's diagnosis discloses to employee the nature of his disability - Jacques v. Farmers Lumber & Supply Co. (1951) Sup. Ct. 47 N.W. 2d 236.

Louisiana: See text of paper, Frisby v. Int. Paper Co. 1954, 76 S. 2d 621.

Maryland: Limitation does not run until employee or someone on his behalf knows he has occupational disease and relationship between disability and occupation. Mutual Chem. Co. v. Pinckney (1954) 106A. 2d 488; Gracie v. Koppers Co. (1957) 130 A 2d. 754.

Massachusetts: Date of injury not date when first treated for lead poisoning but when accumulated effects first incapacitated him - Bergeron's Case (1923) Sup. Jud. Ct. 243 Mass. 366, 137 N.E. 739. Delay until employee knew his injury was probably due to his work may be said to be for reasonable cause in re Wheaton (1942) Sup. Jud. Ct. 310 Mass. 504, 38 N.E. 2d 617.

Michigan: Notice of disablement must be given within time had knowledge or reasonable ground for knowledge of disability Finch v. Ford Motor Co. (1948) 32 N.W. 2d 712.

Minnesota: Time limit runs from time reasonably apparent disability is compensable - Potter v. Midland Corp. (1951) 80 N.W. 2d. 59.

Mississippi: Time begins to run from time employee acquires knowledge of compensable disability. Ingalls Ship Blg. Corp. v. Byrd (1952) Sup. Ct. 60 So. 645. Eczema - Pope Co. v. Wells (1957) Sup. Ct. 370.

Missouri: Statute does not begin to run till it becomes reasonably discoverable compensable injury has been sustained - silicosis - Renfro v. Pittsburgh Plate Glass Co. (1939) 130 S.W. 2d 165.

Nebraska: Time runs from date of knowledge of causal relation Keenan v. Consumers Pub. Power Sup. Ct. (1949) 40 N.W. 2d 261.

New Jersey: Right to compensation accrues at time of disablement not exposure - Biglioli v. Durotest Corp. (1957) A.D. 129 A. 727.

New Mexico: Time runs from time injury could be discovered, but held claimant in this case knew causal connection of knee condition. - Letteau v. Reynolds Electrical & Eng. Co. Sup. Ct. (1955) 290 P. 2d 1072.

Pennsylvania: Limitation runs from date when compensable disability begins and depends on knowledge based on competent medical diagnosis - Ciabattoni v. Birdsboro Steel Foundry & Machine Co. (1956) 386 Pa. 179 125 A. 2d 365.

Tennessee: See cases listed in text.

Texas: Late filing excused where employee did not know seriousness of injury - Texas Employers' Ins. Assn. v. Fricker Ct. of Civ. App. Amarillo (1929) 16 SW 2d 390; Texas Employers' Ins. Assn. v. Hancox Ct. of Civ. App. El Paso (1961) 343 SW 2d 720.

Virginia: Timely notice was given when claim was filed one year after positive diagnosis of disease was communicated to employee - Blue Diamond Coal Co. v. Pannell (1961) 122 SE 2d 666.

Washington: Statute of limitations did not begin to run until claimant given notice by doctor that his disabling disease was occupational in nature and causation - Williams v. Dept. of Labor & Ind. (1954) 277 P. 2d 338.

STATUTORY CONTROL OF RADIATION RECORDS

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> "Some governmental agency should require the keeping of accurate records by all who engage in radiation activities. The records to be kept should be as uniform as possible throughout the various States so as to avoid duplication. Such records should be made available under proper supervision to all interested parties.
>
> It may prove desirable to provide for some kind of central depository (State or federal government, as the case may be) of some of these records. It may also become necessary in the future to require some kind of central recording of the exposure experience of all persons."[1]

The quoted language has an immediacy about it, a sense of present urgency. It expresses a contemporary concern. Yet it is twelve years old. It is part of the report of a workshop on legal problems of atomic energy held at the University of Michigan Law School in 1956.

In 1957, a "Course for Industrial Physicians and Lawyers"[2] was held in Cincinnati under the sponsorship of the University of Cincinnati Medical and Law Schools. The agenda items for the five-day program are remarkably similar to the matters set for discussion at this conference. We were concerned then with the biological effects of radiation; with instrumentation and dosimetry; with the value of various kinds of records, and with legal liability for radiation injury. We still are.

In 1958, the United States Public Health Service sponsored a course on "Public Health Aspects of Radiation"[3] for state and federal officials concerned with radiological health. The two-week course covered such topics as: somatic and genetic effects of radiation on living tissue; use and abuse of radiation in medicine and industry; instrumentation, monitoring and detection; legislation, government control and the legal aspects of radiation injury. The present conference is plowing essentially the same ground.

We have not yet devised a satisfactory system of recording radiation information so that the records will be generally useful in personal injury litigation. There are reasonably effective limited record keeping systems, e.g., records of industrial radiation exposure for workers in the nuclear energy industry, but nothing like the uniform and general records contemplated in the quotation which opens this paper.

This should generate in all of us a certain pessimism, a measure of skepticism. Apparently we have failed to communicate with each other. The scientific mind and the legal mind have not met on common ground in common understanding. Or, if we have communicated, if we have understood each other, perhaps our failure to produce significant results merely indicates that our goal is impractical. Someone may be trying to tell us that universal radiation record keeping is simply not workable.

What Kind of Records Do Litigants Need?

Radiation-exposure records may be kept for informational purposes, in the form of statistics, or otherwise, in order to establish factual bases for research, for the development of health and safety standards, for drafting statues and administrative rules. Many, perhaps most, of the existing radiation records seem to have been designed with this purpose in mind. This appears to be true both of the records kept by private parties and those kept pursuant to a statute or regulation. There is nothing wrong with this and no criticism is intended. A great deal of socially and economically significant data is collected in this way.

However, we are concerned here with another important purpose for keeping radiation-exposure information in records, its utility, or potential utility, in litigation. The two purposes are not necessarily fulfilled by the same kind of records. For instance, litigation-useful records must deal with clearly identified exposure of clearly identified individuals. Statistical, or purely informational records can be more general without impairing their utility. Litigation-useful records must meet the demands of the law of evidence. Informational records need not be concerned with these highly specialized rules. As we shall see later, preparation of a radiation-exposure record which will satisfy the technical rules of legal admissibility is not an easy task. It is not unlikely that many such records already in existence have no value whatever for litigation, and that many currently being made suffer from the same deficiency.

An initial problem then in developing litigation-useful records is to educate a group of record keepers in some fundamental demands of the law of evidence. Doctors, dentists, technicians, the primary record makers, must learn how to build legally valid records. The record must have evidential validity at the time it is made, or it will never be valid. Validity cannot be supplied later by *ex post facto* amendment. The makers of the original record must be taught to think - at least a little bit - like lawyers. I am not encouraged at this prospect.[4] However, it is our first hurdle and it will not be overcome merely by creating regulations and establishing procedures, although simple, direct regulations and clear, easily understood procedures will help. The problem is educational, not legislative.

If, and when, a way is devised of producing the sort of records we need, we must then think in terms of coverage. Many industrial and governmental organizations, universities, laboratories and hospitals keep radiation-exposure records of their employees. These records are, in a sense, self-serving, *i.e.*,a primary purpose of the records is to help these institutions defend themselves from claims of radiation injury by their employees. Nevertheless, the records are also available to the employees themselves in establishing their claims for recovery. It should be noted, however, that these records cover only a very small portion of the United States pupulation. Radiation-exposure record keeping applies to an estimated several hundred thousand people[5] of our two hundred million total.

The great bulk of our population is not presently covered by radiation exposure records kept privately or by public authority. Yet, ever increasing numbers of these people are exposed to diagnostic and therapeutic radiation[6] as well as occupational radiation not reported or reliably recorded anywhere. They include office, clinic and hospital patients, medical and dental technicians, visitors to plants engaged in the radiation industry, and those working with, or exposed to, off-plant radiation sources. They can be counted in the millions. These are the people we are most concerned with in this conference.

In sum, very few existing radiation-exposure records are kept to serve as evidence in litigation and many of these records would be of little use in proving, or disproving, radiation exposure to particular individuals. This problems could be partly solved by educating the primary record makers to the exigencies of the law of evidence. Once sound record keeping practices have been developed, these practices should then be made applicable to everyone who is exposed to radiation, if we really mean to have a record of the "exposure experience of all persons."

Requirements of the Law of Evidence.

Evidence (including records) must be relevant, compentent and material. This simply means that only facts having rational probative value are admissible at trial and that all such facts are admissible unless excluded by some specific rule.[7]

A court will not admit evidence which has no bearing upon any issue in the case. To do so would bury the dispositive facts of the case in an impenetrable mass of valueless data. It would needlessly prolong the trial, clog the docket and increase expenses of litigation. Statements made by a witness as well as documents and records proffered by him may not be evidence of any fact at issue. The trial proceeding is conducted to ascertain the truth of a claim and evidence must tend to that end.

Radiation-exposure records must meet these criteria in order to be admissible as evidence in litigation. Ordinary radiation-exposure records may be susceptible to the objections of counsel on all three grounds. These records are usually based on data acquired from personnel meters (dosimeters) and film badges, or a combination of the two. Some years ago, a perceptive commentator in this field prepared a list of some questions which might be used to impeach the value of film badge evidence. The list does not purport to be inclusive, but the questions raised are still valid.

1. What was the sensitivity range of the film?
2. Was the film ... compared with a control ... exposed to a known amount of radiation?
3. Were the film and its control developed simultaneously in the same developer?
4. What was the temperature of the developing solution?

5. What was the developing time?

6. Were the film and control exposed to different types of radiation...?

7. Were the films read on a densitometer?

8. How was the densitometer zeroed?

9. What ... material was employed to filter out low-energy gamma rays?

10. How was the film identified as being issued to plaintiff?

11. Where were film badges supposed to be worn?

12. Were the badges in fact worn in such positions?

13. Were the film and control exposed to equivalent types of radiation?

14. Is it possible that the badge was shielded from radiation which a great part of the body was receiving?[8]

Still other questions will suggest themselves to the reader. In any event, it is clear that if film badges are to be admissible in personal injury trials, they must be issued, worn and developed under standardized procedures and conditions. Dosimeter recordings suffer from other and different legal infirmities which insure that they will not be admitted into evidence without frequent, and often successful, challenges.

Another factor bearing on the use of radiation-exposure records in the courtroom is provided by the statutory business records exception to the hearsay rule. This legislation eases the admission of certain records. In a trial in a federal court, the federal version of this type of statute might be cited as authority for the admission of radiation-exposure records.

> "In any court of the United States and in any court established by Act of Congress, any writing or record, whether in the form of an entry in a book or otherwise, made as a memorandum or record of any act, transaction, occurrence, or event shall be admissible as evidence of such act,

> transaction, occurrence, or event, if made in regular course of any business, and if it was the regular course of such business to make such memorandum or record at the time of such act, transaction, occurrence, or event or within a reasonable time thereafter.
>
> All other circumstances of the making of such writing or record, including lack of personal knowledge by the entrant or maker, may be shown to affect its weight, but such circumstances shall not affect its admissibility.
>
> The term "business," as used in this section, includes business, profession, occupation, and calling of every kind."[9]

Once the "business regularity" of the record is established it becomes admissible as evidence. Although this type of statute facilitates bringing the record before the court, it does not erase all vestiges of the relevance, competence and materiality doctrine. In addition, there is very grave doubt whether a record for litigation is in the "regular course of business" of a medical office, clinic or hospital.[10]

Our program indicates this conference's sole concern is with the making and controlling of medical radiation-exposure records. We are not concerned with other radiation exposure, occupational or accidental. Our focus is on: patient and personnel dose during diagnostic X-ray examinations; patient and personnel dose during radiotherapy; and patient and personnel dose during radioisotope procedures. Our plaintiffs will be patients and medical personnel; our defendants will be doctors, dentists, technicians, hospitals, clinics and laboratories. Typically a plaintiff will claim injury from the last exposure, or the last several exposures received from the defendant, and the defendant will be interested in producing the plaintiff's lifetime exposure record to refute this claim.

The defendant will want to show that the plaintiff's injury is the result of a cumulation of prior exposures. Since all diagnostic exposures and many therapeutic exposures will be small ones, we are talking of many, many recorded radiation exposures over a broad time span in widely scattered geographical locations. The author can testify from personal experience that more than a score of medical and dental radiation exposures in eight different states is easily possible within a fifty year life span. If such records are to be available for litigation, a central depository should be established where the records will be readily amenable to court process. When this complexity is added to the difficulties we have discussed earlier of developing litigation-useful medical radiation-exposure records, it is clear that the required system will be substantial in terms of personnel and quite expensive.

Control Over the Records.

If we succeed in training the original record makers to develop records with basic evidentiary validity; if we develop suitable machinery to assimilate within this record keeping system the medical radiation-exposure of the population at large; if the system is geared to produce records which are nearly always admissible in evidence; we still must insure the overall reliability and credibility of the system. In other words the quality of the records must be rigidly controlled. Is statutory enactment the best way to do this?

There are three approaches which may be utilized to carry out statutory control of records and record keeping: (a) a nationwide federal statute; (b) uniform state laws; (c) state laws enacted independently in each state. Let us examine all three.

Theoretically, a single federal statute covering the medical radiation exposure of everyone in every state would be ideal. With some public watchfulness the administration of such a statute with an even hand could be assured. The quality of uniformity would be a predominant characteristic of a record keeping system controlled in this manner.

Perhaps this is as good a place as any to point out that "statutory" control is a misnomer. We are really talking about "administrative" or "regulatory" control. A statute is not a suitable vehicle to prescribe a detailed record keeping system such as we need here. Sound principles of public administration call for simple legislation setting the desired policy and directing an agency to fill out the details within prescribed limitations. The agency can then promulgate rules having the force and effect of law to execute and enforce the statutory commands by providing standards, forms and procedures for medical radiation-exposure record keeping. This approach would require the creation of a new federal agency or the establishment of a new division in an existing agency, e.g. the Atomic Energy Commission or the Department of Health, Education and Welfare.

Standardized record keeping can also be achieved through some form of federal-state cooperation with the federal government fixing the basic criteria and the states assisting in their enforcement. The Atomic Energy Commission already has agreements with several states with respect to various aspects of the nuclear energy industry and these agreements seem to work reasonably well.[11] State cooperation could be encouraged by federal grants-in-aid to assist the states in bearing the costs of the operation.

It is never easy to pass a federal law. It is doubly difficult to pass a federal law with little or no glamor. And, the recording of small medical radiation exposures of the entire United States population for speculative utility in litigation with a low probability of incidence is not glamorous. Congress would want to know the cost of the whole system and the number of cases arising from medical radiation exposure in a given year. They would insist on balancing the public interest against the cost of the system. They would do this whether the proposal is for direct federal control or federal-state cooperation. In either event, I do not anticipate great congressional eagerness to spend public money to establish the kind of complex record keeping machinery we have talked about here.

I am reinforced in this pessimistic conclusion by a recent and discouraging precedent. In August and September 1966, Congress held hearings[12] on proposed legislation relating to uniform record keeping for radiation workers. The statutory scheme was tied to improvements in state workmen's compensation laws and provided for federal grants-in-aid to absorb state expense. The proposal was received with vigorous opposition from the states and many associations, corporations and private individuals.[13] The hearing record demonstrates a less than enthusiastic reception from the Joint Committee on Atomic Energy with hard questioning directed to the issue of public good vs. expenditure of public money.[14] The opposition continued even after the Commission had abandoned its demands for improvement in state workmen's compensation laws and had softened its record keeping requirements.[15] The legislation did not pass and this fact does not forecast easy passage of a federal program, or a federal-state cooperative program, of universal medical radiation-exposure record keeping.

It is theoretically possible to secure the uniformity we seek through the agency of a model law drafted by experts and then adopted in each state after the fashion of the American Law Institute's Uniform State Laws. The theory is that the model law will prove to be so attractive that it will be adopted by all our state legislatures in substantially the same form. History offers us little encouragement in this respect. The laws which are adopted are rarely uniform. In addition the process is a slow and tedious one. The model act must be successively sold to the state legislatures. Long and delicate negotiations are often necessary in order to secure enactment at all, much less enactment in substantially the original form.

The third approach to the problem of statutory control of medical radiation-exposure records - state laws independently enacted - is the easiest plan since legislative action in each state is independent of action, or inaction, in any other state and coordination of effort on many fronts is not required. Unfortunately, uniformity of procedures and records would then be incidental and accidental.

Perhaps this would not be quite the catastrophe that so many have assumed. Most personal injury cases are tried in state courts and involve parties and activities within one state. Is there any reason to believe this would not be true in litigation where medical radiation exposure records would be useful? Has any study been made of the incidence of such cases? If we can assume that only a small percentage of medical radiation exposure claims would involve exposures in several states, do we really need a national law and a national agency to control these few cases? For those cases involving interstate exposures, existing principles of the conflict of laws should be adequate to resolve the question of what law to apply. Where interstate parties are involved suit would be brought in the federal courts and, again, there are well-defined rules to determine applicable state laws. This is how we now handle the fact that personal injury law varies in many, many respects from one state to another. It should be remembered that in this age of rapid transportation, instantaneous communication and miraculous copying devices, parties in litigation do not usually have any difficulty in locating all the information they need.

If each state had a sound medical radiation-exposure record keeping system, all the records could be made available wherever needed. If these records were accurate and understandable, the fact that they were not absolutely uniform might not hamper litigation too seriously. Courts and juries should still be able to reach just decisions in contested medical radition exposure claims.

Conclusion.

My subject has been the statutory control of radiation records. My conclusions are several and pessimistic.

1. Development on a large scale of medical radiation-exposure records useful for litigation would require extensive and expensive education of those who make the records in the first instance.

2. Even though our records are made with care and skill and with litigation in mind, the machinery of record keeping must be designed to cover virtually the entire United States population. Very large numbers of our population are now exposed to at least a small amount of medical radiation during their lifetimes. A record keeping system which purports to be national in scope and universal as to persons must be prepared to accommodate all of them.

3. The scientific uncertainty of radiation exposure measurement will open the record of such measurement to vigorous, and often successful, challenge in court.

4. For political, practical and economic reasons, the establishment of a federal, or federal-state, uniform medical radiation-exposure record keeping system is likely to remain a dream.

In view of these conclusions, I recommend that all those who are concerned with radiological health join with interested lawyers in the drafting of a model medical radiation-exposure record keeping act. I recommend that this model act, suitably backed by statistical and economic facts, then be sold to the legislatures of a few of our more populous states. The all-important thing about this statute is that it establish a radiologically and legally valid record keeping system. All other considerations are secondary. After one, two, or three years of experience, the same, or a similar group, should study the results of the statute's operation. Amendments should then be recommended to correct deficiencies. This new study should include proposed modifications to make the statute workable in states where the population is smaller, less transient, or less urban, or differing in other respects from the population in the original group of states. This process of amendment and revision should be a continuous one and, if it is properly and conscientiously done, we will sometime have a universal, reasonably uniform medical radiation-exposure record keeping system suited to the diverse geography and population of this country. If not, I'll be back twelve years from now with the same opening lines for essentially the same paper.

FOOTNOTES

1. Workshops on Legal Problems of Atomic Energy, University of Michigan Law School, September 13-15, 1956, page 38.

2. September 9-13, 1957. Science, government and law were represented on the faculty and in the student body. The author was a member of the faculty for this course.

3. January 13-24, 1958, Washington, D.C. The author was a member of the faculty for this course.

4. Any lawyer who has tried to explain proximate cause or the hearsay rule to a doctor will understand what I mean. Any doctor who has tried to explain medical cause or psychosomatic injury to a lawyer will also understand.

5. In 1966 a member of the Atomic Energy Commission estimated that about 300,000 radiation workers fell within the AEC's jurisdiction and that another 300,000 workers engaged in radiation activity did not. *Proposed Legislation Relating to Uniform Record Keeping and Workmen's Compensation Coverage for Radiation Workers*, Hearings before the Joint Committee on Atomic Energy, 89th Cong., 2d Sess. 52 (1966), hereinafter cited as "Hearings". *See also*, Nuclear Industry, vol. 13, no. 9, Sept. 1966, p.37.

6. More than half of the population of the United States is subjected each year to medical radiological procedures through the use of X-rays or radioisotopes during diagnosis and treatment. Nearly 87,00 X-ray machines were in use in the United States in 1967. *Report of the Medical X-ray Advisory Committee on Public Health Considerations in Medical Diagnostic Radiology (X-Rays)*, U. S. Dept. of Health, Education and Welfare, October 1967, at pp. 1-2.

7. 1 Wigmore, Evidence §§ 9-12, 27-29 (3rd ed. 1940); Conaldson, The Roentgenologist in Court 105-109 (1954).

8. Hutton, *Evidentiary Problems in Proving Radiation Injury* 46 Geo. L. J. 52, 59-60 (1957); *see generally*, Gorson, Suntharalingam, and Thomas, *Results of a Film-Badge Reliability Study*, 84 Radiology 333-346 (Feb. 1965), reprinted in *Hearings supra* note 5, at 344-357; Donaldson, *op. cit. supra* note 7, at 185-217.

9. 28 U.S.C.A. §§ 1732(a). There are similar statutes in all the states, *e.g.*, Calif. Evid. Code § 1271 (1966); Tex. Civ. Stat. Art. 3737e (Cum. Supp. 1968). *See generally*, 2 Wigmore, Evidence § 665; 5 *id.* §§ 1518-1520.

10. The Supreme Court has already indicated that "regular course of business" must find its meaning in the inherent nature of the business in question and in the methods systematically employed for the conduct of the business as a business. *Palmer* v. *Hoffman*, 318 U.S. 109, 11-115 (1943); see also, *Reisman* v. *Los Angeles City School District*, 123 Cal. App. 2d 493, 503-505 (1954).

11. 42 U.S.C.A. § 2021; 10 C.F.R. §§ 150.1-150.30 (1968); *Hearings supra* note 5, at 20.

12. August 30, 31, September 20, 21 and 22, 1966. These are the hearings cited in full in note 5, *supra*.

13. *Hearings supra* note 5, at 365-413, 337-343, 442-444; Nuclear Industry, vol. 13, no. 10, October 1966, pp. 28-31.

14. *Hearings supra* note 5, at pp. 3-89.

15. Nuclear Industry, vol .4, no. 1, January 1967, pp. 24-28; *id.* at vol. 14, no. 6, June 1967, pp. 35-37; *id.* at vol. 14, no. 8, August 1967, pp. 37-38; *id.* at vol. 15, no. 1, January 1968, pp. 25-28; *id.* at vol. 15, no. 8, August 1968, p. 32.

SUMMARY REMARKS

John B. Neibel

We started this conference this morning with an observation of the role of the lawyer in two areas, that of technician inside the legal system and that of social policymaker outside the closed system of law.

I think the morning speakers, primarily Dean White and Dean O'Toole, both took a look from outside the system and raised questions and made the points that there is a need for a reform of the closed system of law to take care of the latent, delayed injury-type problem.

We heard from Mr. Tressler, who indicated in the case of the major accident, that we are covered very adequately by the Price-Anderson Act and its amendments and the indemnity scheme that is inherent in that.

We had disagreement with that viewpoint, though, if you recall, from Mr. Houser, who took the opposite viewpoint and said that reform was not needed; that we should wait until injury became obvious in the case of exposure and that we should use, rather, the traditional procedures of the common law to solve these problems.

This afternoon, we had the view from the inside by Mr. Kronzer and Mr. Alexander, both of whom gave us a very clear picture of the problems faced by the trial lawyer.

I think two conclusions are available to us from the day's proceedings in terms of your record-keeping for purposes of the law: I think almost all of the speakers agree that the medical-scientific fraternity should make an effort to keep more detailed and more accurate records of radiation exposure, both of the accidental type, whether major or minor, and of the intentional exposure-type. I think the points were made that such record-keeping would be for the best because, after all, the thing we are after, whether from the plaintiff's standpoint or the defense, from inside the legal system or out of it, are the facts. As one jurist has said, "They are the hard, obstinate little fellow that won't go away." And that record-keeping will help us to produce truth.

I think the second point in that connection is that the fear of malpractice on the part of the scientific personnel arising out of better record-keeping is an exaggerated fear and that, too, it seems to me, is a fair consensus of the positions taken today. And I think that is critical.

I thank you very much for coming and look forward to seeing the proceedings in print. Thank you.

APPENDIX A

ADDITIONAL SUBMISSIONS

The shortage of time available for questions and statements on the various facets of this conference prohibited many participants from having adequate opportunity to express their opinions. The participants were invited to submit additional comments in writing for possible inclusion in the published proceedings. This appendix contains a selection of the more pertinent letters received.

University of Cincinnati
College of Medicine
November 20, 1968

Dr. Stewart C. Bushong
Department of Radiology
Baylor University
College of Medicine
Texas Medical Center
Houston, Texas 77025

Dear Doctor Bushong:

I have devoted considerable time and effort to the study of radiation accidents over the past seventeen years and have published extensively on this subject. The Handbook on "Medical Aspects of Radiation Accidents" which I edited has sold over 8,000 copies and is about to be reprinted. From these studies and those made as a consultant for the Division of Compliance of the A.E.C., I am disturbed by the continued discussion in regard to record keeping of radiation exposures.

At levels below the MPD as set forth by the NCRP and 10 CFR 20 there have been no instances of human injury. In particular, there is no evidence of somatic injury to adults at any MPD, RPG, or MPC. A recent paper of Saenger, Thoma, and Wald on the "Incidence of Leukemia Following Treatment of Hyperthyroidism," J.A.M.A. 205:855-862, September 16, 1968, shows no leukemogenic effect after a mean dose of 7 - 13 rad to the marrow. With this point in mind it would be difficult to anticipate that any less radiosensitive tumors would be induced at lower doses.

Thus, the compilation of radiation exposure records of several hundred thousand individuals whose doses are less than 5 rem per year in a central repository seems as useful as keeping records of the number of times an individual crosses the street safely.

In 10 CFR 20 part 403, A. and B. regulations are provided for the reporting of exposures above 5 and 25 rem for licensees of the A.E.C. It is frequently not possible to provide more than an educated guess as to the actual doses received and their distributions particularly in instances of contamination. It is baffling to understand why so much attention is paid to keeping of records at low doses and so little interest is expressed in keeping better records for workers exposed at high doses since at present the dosimetry of many of these cases is inadequate.

Insofar as medical exposure is concerned, there is no pertinent information to be obtained from diagnostic procedures nor is it desirable to reconsider the x-ray diary. In spite of all the claims made for the desirability of such records, the imprecision of the doses and the enormous expense of the record keeping effort would make such proposals seem unwise since the cost of health accelerates at about 8% per year without requiring more detailed records than are kept at present.

Hopefully, one would assume that radiation therapists would make their treatment records a permanent part of the patients' charts in a hospital. For office radiotherapy, one would hope that the record would be available as long as the patient needed it. Since such patients constitute only 2% of those using medical radiation, they would be a minor consideration.

Efforts to keep records locally or to provide them to the patients seem desirable. In regard to centralized record keeping the official position of the Board of the Health Physics Society is appended. Since I was a member both of the Ad Hoc Committee and Board, I believe this statement represents my viewpoint.

Sincerely,

/s/

Eugene L. Saenger, M.D.

RECOMMENDATIONS TO THE BOARD OF DIRECTORS OF THE HEALTH PHYSICS SOCIETY FROM THE AD HOC COMMITTEE ON RADIATION EXPOSURE RECORDS

The Ad Hoc Committee at its meetings in Cincinnati and Chicago voted unanimously to make recommendations to the Board of Directors concerning workmen's compensation regulations and radiation exposure records for the purpose of workmen's compensation. After appropriate study and discussions, the Ad Hoc Committee arrived at several conclusions concerning both workmen's compensation laws and radiation records.

1. Workmen's Compensation. The Committee agrees that there are serious deficiencies in workmen's compensation laws in some states and that these laws need improvement. In this connection, the Committee reviewed the 11-point proposal of the AEC (JCAE Hearings, August-September 1966, p.30) and concurs with the proposed standards in substance.

   Recommendations: The Committee recommends that the Board of Directors reaffirm its position that workmen's compensation laws be improved for all workers.

2. Radiation Monitoring and Dosimetry. Radiation monitoring includes personnel monitoring, area monitoring, bioassay and medical examinations.

   The Committee agrees that there are good reasons for carrying out radiation monitoring. The following primary purposes are served:

   (1) To monitor the employee's radiation environment and to evaluate the adequacy of the environmental radiation control program.
   (2) To promote safe radiation working habits on the part of individual employees.
   (3) To document radiation accidents.
   (4) To satisfy the employer's medicolegal requirements as are necessary to protect the employee and his employer.
   (5) To comply with pertinent federal, state and local regulations and laws.

   Recommendations: The Committee agrees that the above purposes are good and sufficient reasons for generating radiation monitoring records.

3. Uniform Record Keeping and Federal Repository. At this time, the Committee could find no plausible scientific justification for a federal repository for routine monitoring records. A simple system of reporting abbreviated information appears even harder to justify on scientific grounds whether it be more economically feasible or not. AEC representatives have indicated three reasons for maintaining centralized records at the federal level: (1) for use in adjudication of workmen's compensation cases, (2) for use in epidemiological studies, and (3) for use in demographical studies. At

the present time, sufficiently complete records for determining the worker's complete exposure history appear unfeasible from a practical viewpoint; employers' detailed data, such as 'logbooks,' usually will be required when it is available. Epidemiology does not appear to be a reasonable basis for the proposed type of centralized records from both the practical and scientific viewpoints. The idea that the records might be useful for demographical purposes appears to be a tertiary afterthought; such studies probably are more readily accomplished from other existing records (e.g. Social Security records).

Recommendations: The Committee recommends that the Board of Directors maintain its current position that there appears to be no scientific basis for the proposed centralized radiation record repository of routine personnel monitoring records. The Committee also recommends that a continuing study be made by the Health Physics Society of the needs for improved record keeping at employer, local, state, and federal levels.

4. Radiation Exposure vs. Radiation Injury and/or Disease. It is possible for an individual to be exposed to radiation in excess of that for Type (a) exposures [10, CFR 20.403 (a)] without overt evidence of injury. It is possible that overt injury, if it occurs at all, may take many years to develop. Nevertheless, an exposed individual may require extensive health physics and medical evaluation in the absence of clinically detectable injury. The exposure incident for such an individual should be recorded for possible future use in case injury develops later.

Recommendations: The Committee recommends that workmen's compensation laws be amended, or other provisions made, so that in the event of an exposure in excess of that for Type (a) [10, CFR 20. 403 (a)], such exposure shall in and of itself constitute a valid reason for review of the case by a competent and impartial panel and that all necessary health physics and medical examinations needed for this review be provided at no cost to the employee. The right to have such a review of his case should not expire with the termination of employment where the exposure occurred.

Adopted by the Board of Directors, Health Physics Society, June 22, 1967

University of California
Lawrence Radiation Laboratory
P. O. Box 808
Livermore, California 94550
December 3, 1968

Dr. Stewart C. Bushong
Assistant Professor of Radiophysics
Baylor University College of Medicine
Texas Medical Center
Houston, Texas 77025

Dear Dr. Bushong:

The interest of Lawrence Radiation Laboratory at Livermore in radiation exposure from medical sources has been sharpened lately, partially as a result of the proposal for a federal central records repository. Basically, we concur with the 1967 position taken by the Health Physics Society in regards to 1) Workmen's Compensation, 2) Radiation Monitoring and Dosimetry, 3) Uniform Record Keeping and Federal Repository, and 4) Radiation Exposure vs. Radiation Injury and/or Disease. (See attached statement.*) The major points of interest were that 1) Workmen's Compensation laws need improving; 2) there are good and sufficient reasons for developing adequate dosimetry techniques and for generating monitoring records; and 3) there is no scientific justification at present for a central federal repository for routine personnel monitoring records.

It becomes increasingly apparent that there is undue emphasis upon and concern for radiation hazards. National and international committees of experts on radiation protection have established conservative occupational limits consistent with the most restrictive effect (genetic response). Appropriate safety factors were applied when exact response relationships were not well known. It appears that we have yet to place this hazard in proper perspective in relationship to other accepted occupational and medical hazards. The benefit to risk ratio is undoubtedly higher for this hazard than for many others we might mention. This point was made at the conference and should be emphasized in the conference record and any subsequent discussions.

As a Health Physicist, I concur with current efforts to reduce unnecessary exposures to a minimum. Statements at the conference indicating that some physicians prescribe more x-rays than necessary in order to protect themselves during possible litigation is evidence of areas where improvement is needed.

Another point of concern was raised in relation to a suggestion that Workmen's Compensation boards restrict or suggest the restriction of occupational exposures to employees when high medical exposures are incurred. This seems impossible to administer with present lack of medical exposure information availability. It further seems scientifically unjustified at the present maximum permissible exposure levels. Again, the radiation protection committees have exempted medical exposures from occupational consideration for valid reasons, which are no less applicable at the present time.

Sincerely,

/s/

Bryce L. Rich, Group Leader
Health Physics & Support Group
Hazards Control Department

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*Editors' note: This statement was also appended to Dr. Saenger's letter, and appears on pp. 366-367.

Brown, Kronzer, Abraham, Watkins & Steely
500 Houston First Savings Building
711 Fannin Street
Houston, Texas 77002
December 2, 1968

Dr. Stewart C. Bushong
Baylor University
School of Medicine
1200 Moursand
Houston, Texas 77025

In Re: Use of Radiation Records in Private Litigation

Dear Doctor Bushong:

I want to draw a conclusion or two reached by me as a result of listening to the presentations by the health physicists, physicists, medical doctors and other scientists interested in the problems raised at your conference. I learned something of value from the Director of the Federal Employers Compensation Bureau and the gentleman defending radiation claims for the AEC.

It occurs to me that it is vitally important to differentiate between the potential value of record keeping in compensation matters and private civil litigation. In the former the hearsay rule and other rules of evidence applicable to common law actions have no real place. Consequently, in undertaking to determine the cause and extent of disability or disease virtually any records may be considered. I believe this was rather clearly illustrated by Mr. Tinsley's examples "A" and "B."

In common law litigation, however, the situation is entirely different. All records being hearsay, no portions are admissible in evidence except as they meet the statutory tests or the common law "shop book" tests for admissibility. This requires that it be determined by the court that the records are not only accurately kept but have a reliability factor that eliminates the necessity of the production of the actual declarant or person making the entry in the records.

In this connection, I listened with great interest to the various scientific speakers and ascertained that it would be a rare situation indeed in which the plaintiff could ever obtain much value from the keeping of records in common law litigation. I specifically refer to those cases in which there is a delayed reaction such as leukemia or blood dyscrasias, disorders that do not manifest themselves shortly after the occurrence. Because most jurisdictions require that the claimant show that his disorder was probably caused (more likely than not) by the exposure, or cumulative exposures, it is most difficult to tie the cause to radiation exposure or exposures.

Texas, for example, is clearly committed to the proposition that the cause of leukemia or cancer can only be established by a qualified expert, and that he must be in a position to express an opinion that based upon reasonable medical probability (more than 51 percent) the cause was related to the particular exposure, or the series of exposures.

Records in radiation cases apparently have some considerable and variable weaknesses. By way of illustration, I understood the various speakers to state that it is not known the exact extent to which each subject assimilates or dissimilates radiation exposures or doses, and the measurement of responses by present methods is most inexact in terms of the area of the body exposed. The use of records recording the film badge readings, and other dosimeter readings, seems to me to be fairly inexact regarding the precise effect that an exposure, or a given group of exposures, may have upon any individual.

As Messrs. Brodsky and Brown indicated, it is perhaps time that we all be "honest" with respect to the inability of the law to cope with the problem of the delayed "injury" resulting from radiation exposures. I think the common law is probably inadequate to deal with these cases on the basis of present legal tests. What is particularly disturbing to me, however, is that radiation records may be most misleading, even though interpretative opinions are excluded. I cannot successfully argue that lay testimony, particularly that of the interested claimant, is a proper substitute, but I do suggest that persons that have any substantial degree of exposure to the potentiality of radiation injuries, should be treated a little bit differently than persons involved in automobile or other traumatic accidents.

By the same token, it occurs to me that defendants will be greatly benefited by record keeping because of the potential inaccuracies that will be shown. It seems that it would be relatively impossible for records to ever be compiled so as to give the plaintiff an even break as to the total amount of whole body exposure. In the first place, no employing group, whether it be in the private sector of the economy, or the government, would ever want to accurately record an excessive dosage for a number of reasons that may not even relate to potential litigation. Certainly in the nuclear medicine fields, and the use of radioactive materials in the treatment of medicine, there would be a subjective desire not to record on the injury side. These are structural or inherent weaknesses that I believe clearly exist.

The man who brought the matter in focus to me was the gentleman who defends cases for the AEC. His desire for these records clearly indicated the ability to defend with their use, and I believe that they are not wholly accurate. They may be the best that we are capable of producing, but that is not the solution to the individual in whose body there is a high degree of probability (although he may not be able to establish it to a moral certainty) that exposures have caused a serious bodily ailment.

I do not deal with the other problems such as leakage, or clear nuclear incidents, or excessive x-ray exposures. In these cases, which are the only type of cases which I have seen, the keeping of records, or the absence of records, might make a material difference. It would be desirable, therefore, that institutions intentionally using radioactive materials be required to keep rather accurate records regarding the care and storage of their materials, the use and dosage, because at least in these present reaction cases there is some more accuracy in the records.

In final analysis, in delayed injury cases I cannot see any great value that will come from record keeping unless there is some relazation of the rule of "probability" so as to permit the recovery where there is a substantial probability that the exposures contributed to cause the ultimate disability.

Again, may I express my pleasure at the privilege of having been asked to participate in the Institute, and enjoyment I had in making new friends.

Sincerely yours,

/s/

W. James Kronzer

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500 Houston First Savings Building
711 Fannin Street
Houston, Texas 77002
January 30, 1969

Dr. Stewart C. Bushong
Baylor University
School of Medicine
1200 Moursand
Houston, Texas 77025

Dear Doctor Bushong:

I thought you would be interested in learning that on January 22 our Supreme Court unfortunately fulfilled my prophecy in the case of Parker v. Employers Mutual Liability Ins. Co. of Wisconsin, 12 T.S.C.J. 200.

The Parker case is a Workmen's Compensation case. Between May, 1962, and April, 1965, Parker was exposed to artificial radiation in the course of his employment. By April, 1965, he had developed a cancer in the left cervical lymph node. On June 15, 1965, a metastatic carcinoma was surgically removed.

A jury in the trial court answered special issues (questions of fact) to the effect that Parker was totally and permanently disabled due to cancer resulting from his exposure, during the course of his employment, to radiation from radioactive materials; the trial court accordingly rendered judgment for him.

The intermediate appellate court reversed and rendered the judgment favoring the insurance carrier, holding: That there was no evidence of a causal connection between petitioner's exposure to radiation and his subsequent development of cancer; that there was no evidence that the cancer complained of was in all medical probability caused by work incurred radiation; and that an inference of causal connection in this case "can be no more than speculation and conjecture."

The Supreme Court notes that although the expert medical witnesses testified that cancer "could have" been caused by radiation, the witnesses also testified that there was no way to determine the cause in this case. The high court holds that the evidence only shows a possible causal connection between the cancer and radiation, rather than a probable connection, and that "the origin and structure of the tumor bears no probable relation in the record to the radiation other than coincidence." Specifically, the Court said:

> "In the absence of factual circumstances of probability understandable to a jury there must be some scientific testimony that can be interpreted as an inference of

> hypothetical probability before we can allow a jury to speculate upon the rights of citizens. * * * To the scientific mind, all things are possible. And with all things possible, citizens would have no reasoned protection from the speculations of courts and juries. * * * With no statutory or common law rules creating an applicable policy otherwise this court must require evidence of a probable causal relation between an injury and act before a case can go to a jury for a decision. The judgment of the Court of Civil Appeals is affirmed."

As I stated in my talk, since cancer and the causes of cancer are considered to be peculiarly within the medical field of expertise, it would be probable that our court would hold that a case for leukemia or cancer could not be made on the basis of probabilities of less than 51 percent. Our Supreme Court now so holds.

The case has considerable significance in that it is the first decision to my knowledge in Texas that directly confronts the question posed in the seminar. I think it forecasts the clear need for legislation with respect to the substantive aspects of the problem of on-the-job injuries.

With kindest personal regards, I am

Sincerely yours,

/s/

W. James Kronzer

HEALTH PHYSICS SOCIETY

November 25, 1968

Stewart C. Bushong, Sc.D.
Assistant Professor of Radiophysics
Baylor University College of Medicine
Texas Medical Center, Dept. of Radiology
Houston, Texas 77025

Dear Stewart:

I had a question which I tried to raise during the Friday meeting but, as you know, we were running behind time and all the people who had questions could not be recognized. I would like to address my question to Dean A. A. White and Dean T. J. O'Toole. It appeared to me that we heard two entirely different recommendations on the handling of radiation cases. I understood Dean White to say that since radiation injuries have latent appearances and since radiation workers work for several employers, a special system of radiation records and a special treatment of radiation litigation is necessary. On the other hand, Dean O'Toole indicated that there are many examples of injuries which have a latent appearance where employees have worked for several employers and therefore no special treatment is needed for the handling of radiation cases. I would like to have each of the men comment on the other man's position.

Sincerely yours,

/s/

Frank L. Paschal, Jr.
Chairman, Health Physics Society
Committee on Radiation Exposure Records

Northeastern University School of Law
Boston, Massachusetts
December 4, 1968

Mr. Frank L. Paschal, Jr.
Chairman, Health Physics Society
c/o General Dynamics/Fort Worth
Post Office Box 748
Fort Worth, Texas 76101

Dear Mr. Paschal:

Dr. Bushong has forwarded to me your letter of November 25.

You are quite right in saying that I took a position directly opposite to that of Dean White. From my own study of claims arising from delayed effects of radiation, I became convinced that the volume of such claims does not warrant the creation of a distinct and elaborate machinery for processing the claims. Furthermore, radiation is not the only agent that produces delayed pathology. An equal case for separate treatment could be made with respect to a substantial number of other industrial substances and processes.

More fortunately, I believe that the existing legal procedures can be adopted to meet this problem fairly and justly. It is for this reason that I seek a re-examination of the legal notion of causation, as contrasted with the medical notion.

In any event, Dean White's proposal does not seem to me to be practical. Many of the persons who are injured by ionized radiation are not engaged in industries in which this is a normal hazard. Some of the claims have come from truckers and shippers, from policemen, and F.B.I. agents, from equipment repairmen, and from an assortment of other callings. These claimants had no reason to anticipate that they would get into a situation where radiation was a hazard. It is not possible to identify a closed class of persons who are occupationally exposed.

The problem of several employers is also not unique to the radiation field. It has been very common with miners. The most common practice is to charge the disease or injury to the most recent employer on the theory that this is a practical solution which over a period of time will not cast an undue burden on any single employer. We also have devices, such as "second injury funds" which can be used to cover these payments so that subsequent employers will not hesitate to hire a worker who has a prior history of exposure.

Dean White's proposal was useful in setting before us the alternative kind of scheme to which we would have to turn if we are unable to make traditional remedies practical and feasible in the radiation field. I remain convinced that we can gain this achievement without costly, radical, and impractical innovation.

Sincerely,

/s/

Thomas J. O'Toole
Dean

General Dynamics
Fort Worth Division
P. O. Box 748
Fort Worth, Texas 76101
December 10, 1968

Dean Thomas J. O'Toole
Northeastern University School of Law
104 The Fenway
Boston, Massachusetts 02115

Dear Dean O'Toole:

Thank you for your prompt reply to the question I raised concerning your talk at the recent Houston meeting. I would like to say that I agree with you wholeheartedly on your position since I too am convinced that traditional handling of radiation injuries and claims can be achieved without costly, radical and impractical innovation.

It is my hope that Dean White will have an equally strong case to support his proposal and that both your reply to the question and Dean White's reply can be included in the written proceedings. It is my thinking that the question raised by your talk and Dean White's was one of the more important ones at the Houston meeting.

I would appreciate it very much if we could keep in touch on the question of radiation injury claims and would like to request that I be put on your mailing list to receive copies of any future talks that you might give on this subject.

Sincerely yours,

/s/

Frank L. Paschal, Jr.
Administrator, Health Physics

University of Houston
Houston, Texas
February 10, 1969

Mr. Frank L. Paschal, Jr.
Chairman, Health Physics Society
c/o General Dynamics/Forth Worth
Post Office Box 748
Fort Worth, Texas 76101

Dear Mr. Paschal:

I have delayed further comment on your letter of November 25, 1968, until the break between semesters gave me a little more time to consider it. I now have the benefit of a copy of Dean O'Toole's letter to you of December 4, 1968, which I will have in mind in making my comments.

I do not have a copy of Dean O'Toole's paper before me, but, as I remember it, he and I were placing emphasis on different aspects of the overall Radiation Injury problem. The emphasis of Dean O'Toole's paper, as I remember it, was on Radiation Injuries occurring in settings covered by some form of workmen's compensation statutes. I meant to be addressing myself wholly to injuries subject to common law actions only. So viewed, I had not felt, to the degree Dean O'Toole seems to feel, that our positions were directly opposite.

Insofar as I have given study to the problem, I am inclined to agree with Dean O'Toole that, with some adjustment in our statutes of limitations and our proof requirements with respect to causation, our workmen's compensation statutes can be made to deal satisfactorily with employment-related radiation injuries. The cases about which I have concern are those injuries unrelated to employment that come from truckers, shippers, policemen, F.B.I. agents, equipment repairmen, housewives, children and other members of the great mass making up the general public. If the claims of these people are to be handled, it will have to be either under existing common law, the common law as modified by statute, or by some comprehensive plan such as that I proposed. It may be that the volume of such claims will never be such as to justify the approach I have suggested. My proposal was made on the assumption that the uses of nuclear energy would become much more commonplace and that the volume of injuries from it would likewise inevitably increase. If that assumption is in error, then the magnitude of the harm resulting from the inadequacies of the common law would be much less than I have envisioned.

But there is, perhaps, a basic disagreement between Dean O'Toole and myself on the adequacy of common law actions to efficiently handle radiation injury cases not covered by workmen's compensation type statutes. Our disagreement would begin, perhaps, over the adequacy of the common law for handling the type of tort litigation with which it has been traditionally concerned. In my opinion, it has bred all to much confusion, waste, delay, outright absurdities and inhumanities to stamp its operation as a significant success. On the point of confusion, I would quote, for one example, from page 314 of Green, Pedrick et al's new case book on Torts:

> "Few tort situations appear more basic than the physical invasions of property by intrusions from neighboring land. Unintended intrusions of such elemental forces as trees, limbs, roots, weeds, animals, fire and water suggest a simple pattern. Yet, an amazing array of theories and doctrines is employed in the cases: (1) trespass; (2) nuisance; (3) negligence; (4) strict liability for escape of artificially impounded substances (Rylands v. Fletcher); (5) strict liability for ultra-hazardous activities; and (6) statutory strict liability.
>
> The picture is further complicated by frequent variations in the formulation and application of each of these theories, and by use of the Sic Utre maxim as if it were a separate theory of liability. Even after the court has chosen its theory of liability in a particular case, there remains the *problem of scope of liability*, frequently discussed in such elusive terms as 'proximate cause', 'foreseeability', 'natural and probable consequences', 'direct' and 'indirect' results, 'sufficient' and 'necessary' causes, 'substantial factor', etc."

An illustration of this confusion is contained in Martin v. Reynolds Metals Company, 342 P^2 790 (Ore. 1959) where there was litigated, at great length, whether the projection by defendant onto plaintiff's land of invisible particles of fluoridic compounds constituted trespass or nuisance. The difference was material only because Oregon pointlessly had a two year statute of limitations for nuisances and a six year statute for trespasses. The Oregon court finally resolved that momentous problem by finding that a trespass resulted. This same company has had to litigate this basic fact situation on theories of trespass, nuisance, strict liability for ultra-hazardous activities, and negligence in the various jurisdictions where it has operated.

Waste arises from the astronomical number of hours spent by lawyers in sterile research on whether a particular set of facts falls into one or the other of these conceptual cubbyholes. What is true of the simple, basic fact situation identified by Green et al is pretty much true of the whole law of torts. We struggle endlessly and wastefully over whether to handle a problem under the concept of duty or proximate cause, or whether the conduct of the defendant constitutes libel, slander or some hybrid of the two.

Much of this pointless hassling causes us to drag our clients through long, delayed trials and appeals that substantially defeat justice regardless of the ultimate outcome.

Pronounced examples of these delays can be found in some recent cases. In Green v. American Tobacco Company, 391 Fed.^{2} 97 (CA5 1968), the court gave directions for entering a judgment on the issue of strict liability against the tobacco company, but sent the case back to have the issue of damages decided by another jury. This was the most recent of many decisions made in litigation that started eleven years before in 1957, and no one now could safely predict how much longer it might go. In 1953, one Pritchard had a cancerous lung removed for which he sued a tobacco company. In 1966, thirteen years later and on the third appeal of the case, (370 Fed.^{2} 95) the court sent the case back for trial on the issues of liability and damages. Again, it would be pure conjecture to estimate when that case would end.

In Overseas Tankship (U.K.) Ltd., a case decided by the Privy Council in 1966, the court was litigating a problem which arose in 1951. This long, dreary process was caused, in substantial part at least, by empty arguments over whether plaintiff's cause of action rested in nuisance or common law negligence and, if negligence, the role foreseeability played in deciding the issue of proximate cause. Another modern day example of confusion and delay can be found in the case of Thornburg v. The Port of Portland, 376 P^2 100 (Ore. 1962); 415 P^2 750 (Ore. 1966). There the court was litigating a fact situation which it is reasonable to assume arose in about 1957, or 1958. In the last decision, eight years and two appeals after the event, the court was reversing and remanding the case for another trial because of an erroneous interpretation by the trial court on the second trial of the decision of the appellate court on the first appeal. What happened on the third trial, if it has yet occurred, is not known.

It is recognized that the foregoing examples are somewhat extreme and few in number buy many, many parallels could be found.

All we have to do to find the massive injustice done by many common law concepts is to follow the history of contributory negligence, assumed risk, the fellow-servant doctrine, the requirement of privity in products liability cases, and the doctrines of charitable and governmental immunity.

So I probably feel much more than does Dean O'Toole, that the common law remedies in tort cases are unduly technical, conceptual, wasteful and, often, harmful. Anyone interested, can find a more comprehensive elaboration of my views in 5 Hous. Law Rev. 575 (1968).

It follows rather naturally that I would have misgivings about entrusting to the common law the solution of the difficult radiation injury cases that I can see arising outside workmen's compensation settings. It is true, as Dean O'Toole states, that other types of situations produce delayed pathology but, for the reasons stated in my paper, I doubt that there are any others that produce non-workmen's compensation cases of such complexity. The differences may well be one of degree only, but Justice Cardozo told us in Schechter Poultry Corp. v. United States, 295 U.S. 495, 554 (1934) that "The law is not indifferent to considerations of degree."

It may very well be that radiation injury problems will come to us so gradually that we may be able to adjust to them and to absorb them into the common law system. The above is a skeleton treatment of some of my misgivings on the point. At any rate, I think the conference and these post-conference discussions may provide some helpful suggestions in coping with the problem, whichever turn it takes.

Very truly yours,

/s/

A.A. White
Professor of Law

APPENDIX B

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